Operator interface	• System control center • Touch-screen monitor • Keyboard and pointing device • Processing module keypad (except for *i*1000SR) • Sample handler keypad (except for *c*4000/*i*1000SR) • Optional bar code scanner
Throughput *c*4000 stand alone:	
• Photometric assays only	Up to 400 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 800 tests per hour
• Individual assay time	Up to 10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *c*8000 stand alone:	
• Photometric assays only	Up to 800 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 1200 tests per hour
• Individual assay time	Up to 10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *c*16000 stand alone:	
• Photometric assays only	Up to 1600 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 1800 tests per hour
• Individual assay time	Up to10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *i*2000 stand alone:	
• General	Up to 200 tests per hour
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment)
Throughput *i*2000SR stand alone:	
• General	Up to 200 tests per hour
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment) 15 minutes (STAT protocol)* *18 minutes estimated processing time including sample handling
Throughput *i*1000SR stand alone:	
• General	Up to 100 tests per hour for One step 11 STAT protocol
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment) 15 minutes (STAT protocol)*

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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i+MED LABORATORIES ISO9001

Certificate of Calibration

Abbott I2000SR

Serial numbe : ISR07603

This certificate is issued in accordance with requirement of specified regulations beyond i+ Med Laboratories Co., Ltd.

Nakhon Pathom Hospital

Panutep B.

Mr.Panutep Boonmajcha
Service Engineer

Mr. Daecha Chankeam
Service Manager

i+MED
LABORATORIES

วันจันทร์ที่ 14 พฤศจิกายน พ.ศ. 2565

(4.2) สัญญาเช่าเครื่อง ทำ-ทุกปี โดยช่างผู้ชำนาญ การของบริษัท

เรื่อง การทำ Preventive Maintenance

เรียน โรงพยาบาลนครปฐม

สิ่งที่ส่งมาด้วย ตารางกำหนดการทำ Preventive Maintenance

เนื่องจากบริษัท ไอเมด ลาบอราทอรี่ จำกัด ได้จัดตารางกำหนดการเข้าทำ Preventive Maintenance ประจำปี 2566 โรงพยาบาลนครปฐม ดังนี้

กำหนดการเข้าทำ PM

Model	S/N	MA	PM
Abbott I2000SR	ISR07603	3 ครั้ง / ปี	1 ครั้ง / ปี

โดยทาง Service Engineer จะทำการติดต่อไปยังเจ้าหน้าที่ห้องปฏิบัติการก่อนการเข้าไปให้บริการตามกำหนดที่ได้ระบุไว้ในตารางการทำ Preventive Maintenance

จึงเรียนมาเพื่อทราบ

ขอแสดงความนับถือ

(นายเดชา จันทร์เขียน)

Service Manager

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

i+MED
LABORATORIES
COMPANY LIMITED

i+MED Laboratories Company Limited
240 Ayothaya Tower,Room No.240/2,240/41, 1st and 20th floor, Ratchadapisek Rd., Huay Kwang, Bangkok 10310
Tel: (66)2 692 5244 Fax: (66)2 692 5245 www.imed.co.th

High-concentration waste bottle:	
• Volume	10 L
• Weight	22 lbs. (10 kg)

i System processing module capacities

Capacities for an *i* System processing modules are presented in the following table.

Table 4.8: i System processing module capacities

Bulk solutions:	
• Pre-Trigger Solution	975 mL
• Trigger Solution	975 mL
• Wash buffer reservoir volume (*i*2000/*i*2000SR)	25 L
• Wash buffer reservoir weight (*i*2000/*i*2000SR)	55 lbs. (25 kg)
• Wash buffer reservoir volume (*i*1000SR)	12 L
• Wash buffer reservoir weight (*i*1000SR)	30 lbs. (14 kg)
Reagent carousel	25* reagent positions available for loading 100 or 500** test kits *Does not include use of reagent kits with > three reagent bottles ** *i*2000/*i*2000SR only
Process path:	
*i*2000/*i*2000SR	112 positions (in both inside and outside track)
*i*1000SR	23 positions
RVs (reaction vessels):	
• Total volume	1000 µL
• Maximum reaction mixture volume	400 µL
RV hopper:	
• *i*2000/*i*2000SR	1200 RVs
• *i*1000SR	360 RVs
Solid waste:	
• Container capacity (*i*2000/*i*2000SR)	5 hours of operation at 200 RVs (reaction vessels) per hour (for a total of 1,000 RVs)
• Waste chute capacity (*i*2000/*i*2000SR only)	15 minutes of run time when the waste container is removed during processing (holds 50 RVs)
• Container capacity (*i*1000SR)	1000 RVs
Liquid waste container (*i*1000SR)	

ARCHITECT™ | Distinguishing features of the ARCHITECT c4000, c8000, c16000, i1000SR, i2000SR, i4000, ci4100, ci8200 and ci16200 systems

	c4000	c8000	c16000	i1000SR
Methods	Photometric, Potentiometric, Turbidimetric	Photometric, Potentiometric, Turbidimetric	Photometric, Potentiometric, Turbidimetric	CHEMIFLEX
Maximum Throughput	Up to 800 tests/hour	Up to 1,200 tests/hour	Up to 1,800 tests/hour	Up to 100 tests/hour
Sample Types	Serum, Plasma, Whole Blood, Urine, CSF	Serum, Plasma, Whole Blood, Urine, CSF	Serum, Plasma, Urine, CSF	Serum, Plasma, Whole Blood, Urine
Sample Tubes	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm
Sample Cup	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)
Sample Capacity	100	215	215	65
Sample Barcode Types	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128
Sample Result Storage	50,000	50,000	50,000	50,000
Sample Volume	1.5–35 µL Average: 6 µL	1.5–35 µL Average: 6 µL	1.5–35 µL Average: 6 µL	10–150 µL Average: 62 µL
Automatic Dilution	Yes	Yes	Yes	Yes
Sample Probe Carryover	<1000 ppm WB to WB ≤0.1 ppm WB to Serum	<1000 ppm WB to WB ≤0.1 ppm WB to Serum	≤0.1 parts per million	≤0.1 parts per million
Reagent Capacity	Up to 90 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 121 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 130 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	25 refrigerated positions
Reagent Type	>95% liquid ready-to-use	>95% liquid ready-to-use	>95% liquid ready-to-use	100% liquid ready-to-use
Reagent Onboard Stability	5–65 days Average: 40 days	5–65 days Average: 40 days	5–65 days Average: 40 days	14–30 days
Calibration Frequency	1–60 days Average: 25 days	1–60 days Average: 25 days	1–60 days Average: 25 days	Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert
Sample, Clot and Bubble Detection	Yes	Yes	Yes	Yes
Reagent Pressure Monitoring	Yes	No	Yes	Yes
Sample Interference Measurement	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	No
System Control Center	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse
Onboard Maintenance Records	Yes	Yes	Yes	Yes
Online Error Code Help	Yes	Yes	Yes	Yes
Host Interface	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available
Remote Diagnostics	AbbottLink	AbbottLink	AbbottLink	AbbottLink
Dimension (H x W x D)	49" x 63" x 36" 125.1 x 160 x 90.7 cm	48" x 79" x 49" 121.9 x 200.6 x 124.5 cm	48" x 79" x 49" 121.9 x 200.6 x 124.5 cm	49" x 59" x 30" 124.5 x 149.9 x 76.2 cm
Weight	1,132 lbs 513.5 Kg	1,425 lbs 646.4 Kg	1,545 lbs 701 Kg	636 lbs 288 Kg
Electrical Requirements	AC 180-264V, 47-63 Hz, 20 amp	AC 180-264V, 47-63 Hz, 20 amp	AC 180-264V, 47-63 Hz, 20 amp	AC 110-120V or 200-240V, ±10%, 50 or 60 Hz self-adjusting
Water Requirements	Deionized water 15 liters/hour during normal operation, 25 liters/hour maximum	Deionized water 25 liters/hour during normal operation	Deionized water ≤54 liters/hour during normal operation	Purified water to dilute buffer concentrate
Heat Output*	3050 BTU/hr, running mode	3400 BTU/hr, running mode	4730 BTU/hr, running mode	2400 BTU/hr, running mode
Sample Loading	RSH	RSH + Carousel	RSH + Carousel	RSH

(+5) เครื่องมีระบบตรวจสอบ ยอดน้ำ และฟองอากาศ (Clot and Bubble Detection) โดยสามารถตรวจจับคุณลักษณะปฏิเสธของสิ่งตรวจวัดได้

*Values provided represent the typical output in "Running" mode for the system processing. Maximum values of 389 BTU/hr was obtained during an internal study. Data is on file with Abbott Diagnostics. the System Control Center (SCC) using the i2000SR as BLANK represents the system. Values obtained during an internal study.

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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i2000SR	i4000SR	ci4100	ci8200	ci16200
CHEMIFLEX	CHEMIFLEX	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Up to 200 tests/hour	Up to 400 tests/hour	Up to 900 tests/hour	Up to 1,400 tests/hour	Up to 2,000 tests/hour
Serum, Plasma, Whole Blood, Urine	Serum, Plasma, Whole Blood, Urine	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm
Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)
135	285	180	365	365
Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128
50,000	50,000	50,000	50,000	50,000
10–150 µL Average: 57 µL	10–150 µL Average: 57 µL	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Yes	Yes	Yes	Yes	Yes
≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million
25 refrigerated positions	50 refrigerated positions	Up to 115 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 146 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 155 refrigerated positions plus patented ISE (Na+, K+, and Cl-)
100% liquid ready-to-use	100% liquid ready-to-use	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
14-30 days	14-30 days	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert	Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Yes	Yes	Yes	Yes	Yes
Yes	Yes	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
No	No	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia
1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse
Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes
Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available
AbbottLink	AbbottLink	AbbottLink	AbbottLink	AbbottLink
48" x 61" x 49" 121.9 x 154.9 x 124.5 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm	49" x 111" x 36" 125.1 x 281.2 x 90.7 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm
1,081 lbs 490.3 Kg	2,162 lbs 980.7 Kg	1,677 lbs 760.7 Kg	2,447 lbs 1109.9 Kg	2,679 lbs 1215 Kg
AC 180-264V, 47-63 Hz,	AC 180-264V, 47-63 Hz	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Purified water to dilute buffer concentrate	Purified water to dilute buffer concentrate	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
4280 BTU/hr, running mode	See i2000SR specifications	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
RSH	RSH	RSH	RSH + Carousel	RSH + Carousel

(4.5) เครื่องมีระบบตรวจสอบคุณภาพการดูดตัวอย่างตรวจ Clot and Bubble detection ได้ และสามารถตรวจสอบปริมาณตัวอย่างที่ดูดได้

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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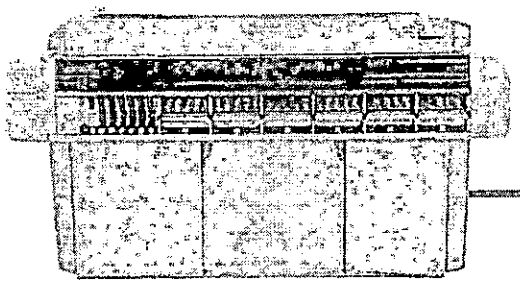
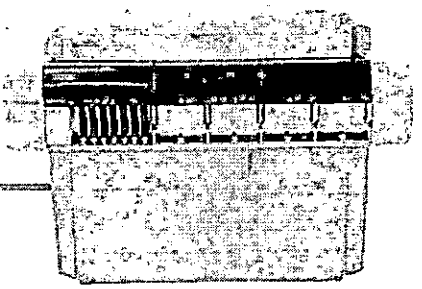
I-MED LABORATORIES COMPANY LIMITED

Integration without compromise.

The ARCHITECT family delivers advanced technology, with a simple and consistent user experience, enabling consolidation of clinical chemistry and immunoassay on a single platform. (4.6) เครื่องตรวจวิเคราะห์ทางอิมมูโนโลยี ที่ตอบสนองระบบการเชื่อมต่อกับเครื่องตรวจวิเคราะห์ทางเคมี



c16000



i2000SR

ARCHITECT integration achieves testing consolidation.

- ☐ Excellent STAT turnaround time
- ☐ Ease of use
- ☐ Improved workflow
- ☐ Confidence in results
- ☐ Reduced costs

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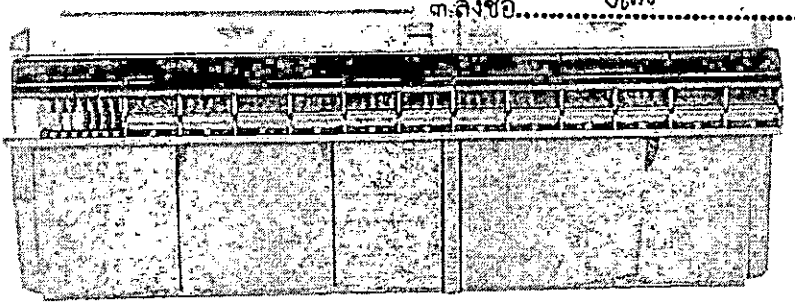
๓.ลงชื่อ.....กรรมการ



ci16200

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ชั้น 30 และชั้น 33 ถนนสาทรใต้
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Fax/แฟกซ์ : + 66 2 655 4017
Diagnostics/
Diabetes Care Tel/โทร : +66 2 697 2888
Website www.abbott.co.th

Abbott

(4.1) หนังสือรับรอง การเป็นตัวแทนจำหน่ายชั้น เครื่องตรวจวิเคราะห์และน้ำยา

หนังสือรับรอง

โดยหนังสือฉบับนี้ บริษัท ไอเมด ลาบอราทอรี่ จำกัด สำนักงานตั้งอยู่เลขที่ 240 อาคารอโยธยา ทาวเวอร์ ห้องเลขที่ 240/2 , 240/41 ชั้น 1, 20 ถนนรัชดาภิเษก แขวงห้วยขวาง เขตห้วยขวาง กรุงเทพมหานคร 10310 เป็นตัวแทนจำหน่ายผลิตภัณฑ์ของ บริษัท แอ็บบอต ลาบอแรตอรีส จำกัด (สหรัฐอเมริกา) ในประเทศไทย โดยมีอำนาจในการจำหน่ายส่งเสริม และให้บริการผลิตภัณฑ์ในด้านโลหิตวิทยา เคมีคลินิค และภูมิคุ้มกันวิทยา

ดังนั้น บริษัท ไอเมด ลาบอราทอรี่ จำกัด ได้รับมอบอำนาจให้เป็นผู้มีสิทธิ์ในการยื่นเอกสารสำคัญต่างๆ ที่ต้องการใช้ในการสอบราคา การเปิดซองประมูล และประกวดราคาของผลิตภัณฑ์ต่างๆ ของบริษัทฯ เป็นระยะเวลา นับตั้งแต่ 3 มกราคม 2566 – 31 ธันวาคม 2566

หนังสือฉบับนี้ออกให้ ณ วันที่ 3 มกราคม 2566

บริษัท แอ็บบอต ลาบอแรตอรีส จำกัด

(นางธนิดา เชาวน์ลิศ / นายสุริยะ นารายณ์ เมฆอน)

General Manager / General Manager

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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i-MED LABORATORIES COMPANY LIMITED

ARCHITECT™ | Distinguishing features of the ARCHITECT

c4000, c8000, c16000, i1000SR, i2000SR, i4000SR, ci4100, ci8200 and ci16200 systems

	c4000	c8000	c16000	i1000SR
Methods	Photometric, Potentiometric, Turbidimetric	Photometric, Potentiometric, Turbidimetric	Photometric, Potentiometric, Turbidimetric	CHEMIFLEX
Maximum Throughput	Up to 800 tests/hour	Up to 1,200 tests/hour	Up to 1,800 tests/hour	Up to 100 tests/hour
Sample Types	Serum, Plasma, Whole Blood, Urine, CSF	Serum, Plasma, Whole Blood, Urine, CSF	Serum, Plasma, Urine, CSF	Serum, Plasma, Whole Blood, Urine
Sample Tubes	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm
Sample Cup	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)
Sample Capacity	100	215	215	65
Sample Barcode Types	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128
Sample Result Storage	50,000	50,000	50,000	50,000
Sample Volume	1.5–35 µL Average: 6 µL	1.5–35 µL Average: 6 µL	1.5–35 µL Average: 6 µL	10–150 µL Average: 62 µL
Automatic Dilution	Yes	Yes	Yes	Yes
Sample Probe Carryover	<1000 ppm WB to WB ≤0.1 ppm WB to Serum	<1000 ppm WB to WB ≤0.1 ppm WB to Serum	≤0.1 parts per million	≤0.1 parts per million
Reagent Capacity	Up to 90 refrigerated positions plus patented ISE (Na^+, K^+, and Cl^-)	Up to 121 refrigerated positions plus patented ISE (Na^+, K^+, and Cl^-)	Up to 130 refrigerated positions plus patented ISE (Na^+, K^+, and Cl^-)	25 refrigerated positions
Reagent Type	>95% liquid ready-to-use	>95% liquid ready-to-use	>95% liquid ready-to-use	100% liquid ready-to-use
Reagent Onboard Stability	5–65 days Average: 40 days	5–65 days Average: 40 days	5–65 days Average: 40 days	14-30 days
Calibration Frequency	1–60 days Average: 25 days	1–60 days Average: 25 days	1–60 days Average: 25 days	Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert
Sample, Clot and Bubble Detection	Yes	Yes	Yes	Yes
Reagent Pressure Monitoring	Yes	No	Yes	Yes
Sample Interference Measurement	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	No
System Control Center	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse
Onboard Maintenance Records	Yes	Yes	Yes	Yes
Online Error Code Help	Yes	Yes	Yes	Yes
Host Interface	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available
Remote Diagnostics	AbbottLink	AbbottLink	AbbottLink	AbbottLink
Dimension (H x W x D)	49" x 63" x 36" 125.1 x 160 x 90.7 cm	48" x 79" x 49" 121.9 x 200.6 x 124.5 cm	48" x 79" x 49" 121.9 x 200.6 x 124.5 cm	49" x 59" x 30" 124.5 x 149.9 x 76.2 cm
Weight	1,132 lbs 513.5 Kg	1,425 lbs 646.4 Kg	1,545 lbs 701 Kg	636 lbs 288 Kg
Electrical Requirements	AC 180-264V, 47-63 Hz, 20 amp	AC 180-264V, 47-63 Hz, 20 amp	AC 180-264V, 47-63 Hz, 20 amp	AC 110-120V or 200-240V, ±10%, 50 or 60 Hz self-adjusting
Water Requirements	Deionized water 15 liters/hour during normal operation, 25 liters/hour maximum	Deionized water 25 liters/hour during normal operation	Deionized water ≤54 liters/hour during normal operation	Purified water to dilute buffer concentrate
Heat Output*	3050 BTU/hr, running mode	3400 BTU/hr, running mode	4730 BTU/hr, running mode	2400 BTU/hr, running mode
Sample Loading	RSH	RSH + Carousel	[illegible]	RSH

(๔.๘) เครื่องสามารถบรรจุสิ่งส่งตรวจได้ไม่น้อยกว่า 130 ตัวอย่าง

*Values provided represent the typical output in "Running" mode for the system processing module and sample handler. A maximum value of 389 BTU/hr was obtained for the System Control Center (SCC) using the i2000SR as BLANK representative system. Values obtained during an internal study. Data is on file with Abbott Diagnostics.

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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๒.ลงชื่อ...กรรมการ

๓.ลงชื่อ...กรรมการ

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i2000SR	i4000SR	ci4100	ci8200	ci16200
CHEMIFLEX	CHEMIFLEX	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Up to 200 tests/hour	Up to 400 tests/hour	Up to 900 tests/hour	Up to 1,400 tests/hour	Up to 2,000 tests/hour
Serum, Plasma, Whole Blood, Urine	Serum, Plasma, Whole Blood, Urine	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm	Height: 72–102 mm Diameter: 9.6–16.1 mm
Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)	Yes (50 µL dead volume)
135	285	180	365	365
Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128	Code 39, Codabar, Interleaved 2 of 5, Code 128
50,000	50,000	50,000	50,000	50,000
10–150 µL Average: 57 µL	10–150 µL Average: 57 µL	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Yes	Yes	Yes	Yes.	Yes
≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million	≤0.1 parts per million
25 refrigerated positions	50 refrigerated positions	Up to 115 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 146 refrigerated positions plus patented ISE (Na+, K+, and Cl-)	Up to 155 refrigerated positions plus patented ISE (Na+, K+, and Cl-)
100% liquid ready-to-use	100% liquid ready-to-use	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
14-30 days	14-30 days	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert	Calibrate with new lot number, if controls are out of range or if specified otherwise within the package insert	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Yes	Yes	Yes	Yes	Yes
Yes	Yes	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
No	No	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia	Yes, hemolysis, icterus, and lipemia
1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse	1 SCC, with color touchscreen monitor, keyboard, and mouse
Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes
Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available	Bidirectional, serial RS-232 interface, host query option available
AbbottLink	AbbottLink	AbbottLink	AbbottLink	AbbottLink
48" x 61" x 49" 121.9 x 154.9 x 124.5 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm	49" x 111" x 36" 125.1 x 281.2 x 90.7 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm	48" x 127" x 49" 121.9 x 322.6 x 124.5 cm
1,081 lbs 490.3 Kg	2,162 lbs 980.7 Kg	1,677 lbs 760.7 Kg	2,447 lbs 1109.9 Kg	2,679 lbs 1215 Kg
AC 180-264V, 47-63 Hz,	AC 180-264V, 47-63 Hz	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
Purified water to dilute buffer concentrate	Purified water to dilute buffer concentrate	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
4280 BTU/hr, running mode	See i2000SR specifications	See c4000 and i1000SR specifications	See c8000 and i2000SR specifications	See c16000 and i2000SR specifications
RSH			[illegible]usel	RSH + Carousel

(48) เครื่องสำรอง 135 กระดูกล้างส่งตรวจได้ ไม่น้อยกว่า 130 ตัวอย่าง

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.............................ประธานกรรมการ

๒.ลงชื่อ.............................กรรมการ

๓.ลงชื่อ.............................กรรมการ

I-MED LABORATORIES COMPANY LIMITED

Sample handlers

The sample handler is a transport system used for loading calibrators, controls, and patient samples and presenting them to the processing module(s).

A single primary sample handler transports samples through an ARCHITECT System regardless of the number of processing modules and types.

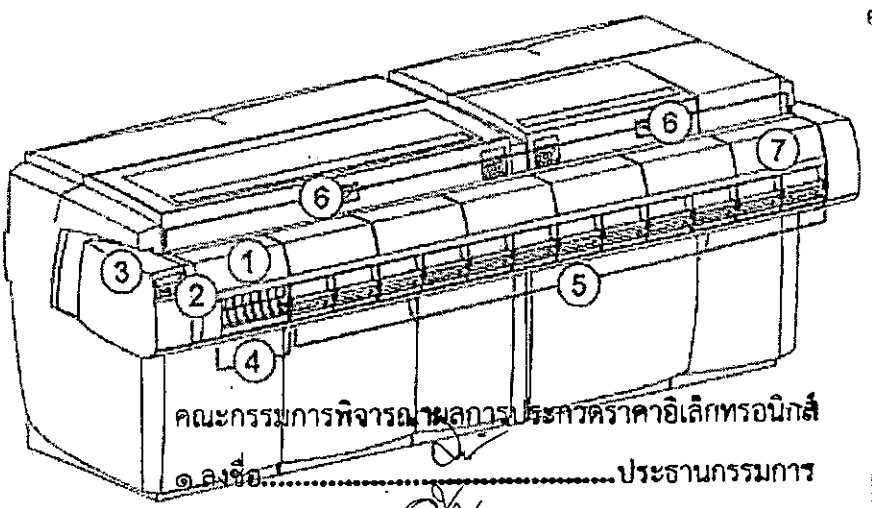
NOTE: Unless otherwise indicated, the term sample handler is used generically throughout this documentation to refer to all configurations.

Sample handler topics include:

RSH - robotic sample handler (*c*8000/*c*16000/*i*2000SR)

The RSH (robotic sample handler) is a transport system used for loading calibrators, controls, and patient samples and presenting them to a *c*8000/*c*16000 and/or *i*2000SR processing module. The design of the RSH allows random and continuous access, and sample positioning for automatic retesting. Two types of bays position samples for either routine or priority processing.

Figure 1.177: Robotic sample handler components (c8000/c16000/i2000SR)



Legend:

1. RSH cover: Provides access to the RSH components.

Operator interface	• System control center • Touch-screen monitor • Keyboard and pointing device • Processing module keypad (except for *i*1000SR) • Sample handler keypad (except for *c*4000/*i*1000SR) • Optional bar code scanner
Throughput *c*4000 stand alone:	
• Photometric assays only	Up to 400 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 800 tests per hour
• Individual assay time	Up to 10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *c*8000 stand alone:	
• Photometric assays only	Up to 800 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 1200 tests per hour
• Individual assay time	Up to 10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *c*16000 stand alone:	
• Photometric assays only	Up to 1600 tests per hour
• ICT (integrated chip technology) assays only	Up to 600 tests per hour
• Photometric and ICT assay mix	Up to 1800 tests per hour
• Individual assay time	Up to10 minutes
• Warm-up time from cold start	Approximately 30 minutes
Throughput *i*2000 stand alone:	
• General	Up to 200 tests per hour
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment)
Throughput *i*2000SR stand alone:	
• General	Up to 200 tests per hour
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment) 15 minutes (STAT protocol)* *18 minutes estimated processing time including sample handling
Throughput *i*1000SR stand alone:	
• General	Up to 100 tests per hour for One step 11 STAT protocol
• Time to first result	29 minutes (non-pretreatment) 36 to 43 minutes (pretreatment) 15 minutes (STAT protocol)*

ARCHITECT

SYSTEM

en

AFP

REF 3P36

B3P360

G6-2601/R06

Read Highlighted Changes
Revised October 2015

AFP

Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number	CONTROL NO.	Control Number
IVD	*In Vitro* Diagnostic Medical Device	REACTION VESSELS	Reaction Vessels
LOT	Lot Number	REAGENT LOT	Reagent Lot
	Expiration Date	REPLACEMENT CAPS	Replacement Caps
SN	Serial Number	SAMPLE CUPS	Sample Cups
SEPTUM	Septum	WARNING: SENSITIZER	Warning: May cause an allergic reaction
2°C 8°C	Store at 2-8°C	CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
		GTIN	Global Trade Item Number
	Consult instructions for use	PRODUCT OF IRELAND	Product of Ireland
	Manufacturer	INFORMATION FOR USA ONLY	Information needed for United States of America only

See REAGENTS section for a full explanation of symbols used in reagent component naming.

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

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๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

Abbott

i-MED LABORATORIES COMPANY LIMITED

WARNING: The concentration of alpha-fetoprotein (AFP) in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the AFP assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining AFP levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST:

1. For Cancer Management - Confirm baseline values for patients being serially monitored.
2. For Prenatal Testing - Establish a range of expected values for the new assay based on serum or plasma and amniotic fluid from pregnant women with confirmed gestational age.

Caution: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory, and use is restricted to, by, or on the order of a physician.

NAME

ARCHITECT AFP

INTENDED USE

The ARCHITECT AFP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of alpha-fetoprotein (AFP) in:

1. Human serum or plasma to aid in monitoring disease progression during the course of disease and treatment of patients with nonseminomatous testicular cancer.
2. Human serum, plasma and amniotic fluid at 15 to 21 weeks gestation to aid in the detection of fetal open neural tube defects (NTD). Test results when used in conjunction with ultrasonography or amniography are a safe and effective aid in the detection of fetal open NTD.

SUMMARY AND EXPLANATION OF TEST

The discovery of alpha-fetoprotein (AFP) in fetal serum was first recorded by Bergstrand and Czar in 1956.[1] Alpha-fetoprotein is a single polypeptide chain glycoprotein with a molecular weight of approximately 70,000 daltons. The physicochemical properties and amino acid composition are similar to those of albumin.[2,3] Synthesis of AFP occurs primarily in the liver and yolk sac of the fetus. It is secreted into fetal serum, reaching a peak at about 13 weeks gestation and gradually declining thereafter. Elevated serum AFP levels subsequently reappear during pregnancy and in conjunction with several malignant diseases.

Cancer Management

Alpha-fetoprotein (AFP) was first described as a human tumor-associated protein in 1964 by Tatarinov.[4] Since then, it has been shown that elevation of serum AFP above values typically found in healthy individuals occurs in several malignant diseases,[5-8] most notably nonseminomatous testicular cancer and primary hepatocellular carcinoma. In the case of nonseminomatous testicular cancer, a direct relationship has been observed between the incidence of elevated AFP levels and the stage of disease.[9,10] Elevated AFP levels have also been observed in patients diagnosed as having seminoma with nonseminomatous elements but have not been observed in patients with pure seminoma.[9,11,12] Human chorionic gonadotropin (hCG) and AFP are also important prognostic indicators of survival rate among patients with advanced nonseminomatous germ cell testicular tumors.[13]

The usefulness of AFP measurements in the management of patients with nonseminomatous testicular cancers has been well documented.[7,11,14] For patients in clinical remission following treatment, AFP levels generally decrease.[11] Post-operative AFP values which fail to return to normal strongly suggest the presence of residual tumor.[6,7,11] Tumor recurrence is often accompanied by a rise in AFP before progressive disease is clinically evident.[7,9]

Greater than 70% of patients with primary hepatocellular carcinoma have been reported to have elevated levels of serum AFP.[5,8,15] Elevated AFP levels have occasionally been found in association with gastrointestinal tract cancers with and without liver metastases[16] and only rarely in other malignancies.[5,8] Serum AFP has been found to be elevated during pregnancy, in diseases such as ataxia telangiectasia, hereditary tyrosinemia, teratocarcinoma and in benign hepatic conditions such as acute viral hepatitis, chronic active hepatitis and cirrhosis.[6,15,17] Elevation of serum AFP in benign hepatic diseases is usually transient.[6]

AFP testing is not recommended as a screening procedure to detect cancer in the general population.

Prenatal Testing

Many studies have confirmed the utility of AFP in the early detection of fetal open neural tube defects (NTD).[19-20] In the US, NTD, primarily anencephaly and spina bifida, occur at the rate of between 1 and 2 per 1000 live births and are among the most common major congenital malformations.[21,31] The incidence of NTD varies geographically and across racial groups.[22-26]

Anencephaly is incompatible with life and accounts for one-third to one-half of all NTD. Open spina bifida can vary widely in severity.

Reports from the scientific literature suggest additional factors to be considered when assessing the risk of an NTD being present.[22-28] One is the effect of maternal weight. Maternal blood volume, as reflected by maternal weight, has been reported to affect maternal serum AFP (MSAFP) concentration in maternal circulation; the higher the maternal weight, the lower the MSAFP concentration.[26-29] Another factor to consider is maternal diabetes. Insulin dependent diabetic women reportedly have MSAFP levels significantly lower than non-diabetic women and an increased incidence of NTD.[27,28,30] Maternal serum AFP levels in the black population average about 10% higher than MSAFP values in the non-black population. An adjustment factor or use of an appropriate normative data base have been suggested in the literature.[25,26]

Amniotic fluid AFP (AFAFP) levels peak at about 13 weeks gestation after which they rapidly decline until about 22 weeks gestation and then gradually decline until term. Transfer of AFP into maternal circulation is accomplished primarily through diffusion across the placenta.[31] If the fetus has an open neural tube defect, AFP is thought to leak directly into the amniotic fluid (AF) causing unexpectedly high levels of AFAFP. Subsequently, the AFAFP reaches the maternal circulation, thus producing abnormally elevated levels of MSAFP. Certain fetal abnormalities such as congenital renal disease and esophageal atresia also show AFAFP elevations.[32,33] Other fetal distress situations such as omphalocele or gastroschisis, defective kidneys, threatened abortion, prematurity and sometimes fetal demise[34-37] may exhibit abnormally high levels of MSAFP. Increased MSAFP values are also seen in multiple pregnancies[38] and in normal singleton pregnancies in which the gestational age has been underestimated. Low MSAFP values have been associated with molar pregnancy, missed abortion, pseudocyesis, overestimated gestational age and Down Syndrome.[29,39]

In a report on over 18,000 pregnancies, the U.K. Collaborative Study has established multiples of the median (MoM) as the preferred way to express AFP results.[18] The median AFP value for each gestational week is first determined; then individual AFP levels are reported as multiples of this value. This method of expression facilitates comparison of AFP test results across gestational weeks and between laboratories.

AFP testing during pregnancy is recommended as an effective way to determine those women potentially at risk of carrying a fetus affected with an open NTD. Used in conjunction with other confirmatory procedures such as ultrasonography or amniography, measurement of AFP serves as an important tool in the care and management of these patients.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT AFP assay is a two-step immunoassay for the quantitative measurement of AFP in human serum, plasma and amniotic fluid using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-AFP coated paramagnetic microparticles are combined. AFP present in the sample binds to the anti-AFP coated microparticles. After washing, anti-AFP acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of AFP in the sample and the RLUs detected by the ARCHITECT *i* System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Reagent Kit, 100 Tests/500 Tests

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT *i* Systems. Please contact your local distributor.

ARCHITECT AFP Reagent Kit (3P36)

- MICROPARTICLES 1 or 4 Bottle(s) (6.6 mL/27.0 mL) Anti-AFP (mouse, monoclonal) coated microparticles in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.1% solids. Preservative: ProClin 300.
- CONJUGATE 1 or 4 Bottle(s) (5.9 mL/26.3 mL) Anti-AFP (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 400 ng/mL. Preservatives, antimicrobial agents and sodium azide.

ARCHITECT CEA

REF 7K68-27
REF 7K68-22
REF 7K68-35
REF 7K68-32

en
CEA
7K68
G6-2827/R04
B7K6R0

Read Highlighted Changes: Revised November 2015.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: The concentration of CEA in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CEA assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CEA levels serially is changed, additional sequential testing should be carried out. Before changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

CAUTION: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician.

NAME

ARCHITECT CEA (carcinoembryonic antigen)

INTENDED USE

The ARCHITECT CEA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Carcinoembryonic Antigen (CEA) in human serum and plasma. The ARCHITECT CEA assay is to be used as an aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

SUMMARY AND EXPLANATION OF THE TEST

Carcinoembryonic antigen (CEA), first described in 1965 by Gold and Freedman,[1] is a tumor associated antigen. CEA was characterized as a glycoprotein of approximately 200,000 molecular weight with a β-electrophoretic mobility.[2, 3] Subsequent development of a radioimmunoassay (RIA) by Thomson, et al[4] made it possible to detect the very low concentrations of CEA in blood, other body fluids, and also in normal and diseased tissues.[5-7] Two years later, Hansen, et al[8] developed a modified RIA for CEA.

The result of clinical studies to date indicate that CEA, although originally thought to be specific for digestive tract cancers, may also be elevated in other malignancies and in some nonmalignant disorders.[9-15]

CEA testing can have significant value in the monitoring of patients with diagnosed malignancies in whom changing concentrations of CEA are observed. A persistent elevation in circulating CEA following treatment is strongly indicative of occult metastatic and/or residual disease.[16-20]

A persistently rising CEA value may be associated with progressive malignant disease and a poor therapeutic response.[21-23] A declining CEA value is generally indicative of a favorable prognosis and a good response to treatment.[21, 23, 24] Patients who have low pretherapy CEA levels may later show elevations in the CEA level as an indication of progressive disease.[25]

Clinical relevance of the CEA assay has been shown in the follow-up management of patients with colorectal, gastric, breast, lung, prostatic, pancreatic, and ovarian carcinoma.[18, 24, 26-31] Follow-up studies of patients with colorectal, breast, and lung carcinoma suggest that the preoperative CEA level has prognostic significance.[32-35] CEA testing is not recommended as a screening procedure to detect cancer in the general population; however, use of the CEA test as an adjunctive test in predicting prognosis and as an aid in the management of cancer patients has been widely accepted.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CEA assay is a two-step immunoassay to determine the presence of CEA in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and anti-CEA coated paramagnetic microparticles are combined. The CEA present in the sample binds to the anti-CEA coated microparticles.
2. After washing, anti-CEA acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of CEA in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT CEA 7K68

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	7K68-27	7K68-22	7K68-35	7K68-32
Σ	100	400	500	2000
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL	4 x 26.3 mL

MICROPARTICLES anti-CEA (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.1% solids. Preservative: Antimicrobial Agents.

CONJUGATE anti-CEA (mouse, monoclonal) acridinium-labeled Conjugate in phosphate buffer with protein (bovine) stabilizer. Minimum concentration: 0.8 µg/mL. Preservative: Antimicrobial Agents.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

NOTE: Bottle and volume varies based on order.

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์
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๒.ลงชื่อ.....กรรมการ
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Z+MED LABORATORIES COMPANY LIMITED

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(4.13) มีการทำแผนในการบำรุงรักษา (Preventive maintenance)

ตารางกำหนดการทำ MA/PM

ประจำปี 2566

โรงพยาบาลนครปฐม

Model	S/N	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	MA	PM
Abbott I2000SR	ISR07603		MA			MA			PM			MA		3ครั้ง/ปี	1ครั้ง/ปี

หมายเหตุ

MA (Maintenance) : คือการตรวจสอบสภาพเครื่อง และทำความสะอาดส่วนต่างๆ ของเครื่อง และทดสอบการทำงานของเครื่องให้เป็นไปตามคู่มือของเครื่อง

PM (Preventive Maintenance) : คือการตรวจสอบสภาพเครื่อง และทำความสะอาดส่วนต่างๆ ของเครื่อง เปลี่ยนอะไหล่ตามอายุการใช้งาน และทดสอบการทำงานของเครื่องให้เป็นไปตามคู่มือของเครื่อง

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i-MED LABORATORIES COMPANY LIMITED

ARCHITECT Total PSA

REF 7K70-25
REF 7K70-20
REF 7K70-35
REF 7K70-30

en
Total PSA
7K70
G47685R07
B7K700

Read Highlighted Changes: Revised May 2019.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: The concentration of Total PSA in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the Total PSA assay used. Values obtained with different assay methods, including Abbott PSA assays, cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining Total PSA levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

NAME

ARCHITECT Total PSA (Prostate Specific Antigen)

INTENDED USE

The ARCHITECT Total PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Total PSA (both Free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum:

1. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostatic biopsy is required for diagnosis of cancer.
2. As an adjunctive test to aid in the management of prostate cancer patients.

SUMMARY AND EXPLANATION OF THE TEST

Prostate specific antigen (PSA), a member of the human kallikrein gene family, is a serine protease with chymotrypsin-like activity. The mature form of PSA is a single chain glycoprotein of 237 amino acids containing 7-8% carbohydrate as a single N-linked oligosaccharide side chain. PSA has a molecular weight of approximately 30,000 daltons.[1, 8, 37, 38]

The major site of PSA production is the glandular epithelium of the prostate. PSA has also been found in breast cancers, salivary gland neoplasms, periurethral and anal glands, cells of the male urethra, breast milk, blood and urine.[1, 2] PSA produced in the prostate is secreted into the seminal fluid in high concentrations. A major function of PSA is the proteolytic cleavage of gel-forming proteins in the seminal fluid, resulting in the liquefaction of the seminal gel and increased sperm mobility.[1] Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. Increasing levels of serum PSA are associated with prostatic pathology, including prostatitis, benign prostatic hyperplasia (BPH), and cancer of the prostate.[1, 3-7]

PSA occurs in three major forms in blood. The major immunodetectable form is PSA complexed with the serine protease inhibitor, alpha-1-antichymotrypsin (PSA-ACT). Uncomplexed, or Free PSA, is the other immunodetectable form of PSA in serum. The majority of Free PSA in serum appears to be an inactive form that cannot complex with protease inhibitors and may be either a PSA zymogen or an enzymatically-inactive, cleaved form of PSA. Equimolar-response PSA assays have an equivalent response to both Free PSA and PSA-ACT.[1] The ARCHITECT Total PSA assay is an equimolar assay. A third form of PSA, a complex with alpha-2-macroglobulin, is not detectable with current immunoassays for PSA due to the engulfment and subsequent masking of PSA epitopes by the alpha-2-macroglobulin molecule.[1, 8, 9]

Prostate cancer is the most frequently diagnosed cancer and the second leading cause of cancer deaths in men in the United States.[10] Early diagnosis of carcinoma of the prostate is hindered by the lack of symptoms in men with localized tumors. Therefore, early detection requires a simple, safe, and inexpensive test for the disease in asymptomatic men. The traditional method for detection of prostate cancer is the digital rectal examination (DRE). However, only 30 to 40% of cancers detected by DRE screening are expected to be confined to the prostate. The frequent finding of locally advanced prostate cancer in screened patients may be due to the inability of DRE to detect tumors of small volume that are most likely to be confined to the prostate.[11] Since patients with small tumors are believed to have the best prognosis, it can be concluded that DRE has limited sensitivity in detecting those tumors with the greatest potential for cure.[12]

In a 1990 publication by Cooner et al., data was presented regarding the clinical use of other diagnostic modalities such as prostate ultrasonography and serum prostate specific antigen for early detection of prostate cancer. This study found that there was a significant increase in predictability for cancer when the DRE and PSA tests were abnormal.[13] Several other studies have shown that the measurement of serum PSA concentrations offers several advantages in the early detection of prostate cancer. The procedure is more acceptable to patients, the result is objective and quantitative, and is independent of the examiners skill. In several recent studies of healthy men 50 years or older, serum PSA levels had the greatest ability to predict prostate cancer. These studies concluded that not only is serum PSA measurement a useful addition to rectal examination and ultrasonography in the detection of prostate cancer, but that it is also the most accurate of the three tests for this purpose.[14, 15] In January 1992, the American Urological Association endorsed annual examination with DRE and PSA, for early detection of prostate cancer, beginning at age 50.[16] This was reaffirmed by the American Cancer Society in November 1992.[17] The combined use of DRE and PSA has been shown to result in an increased detection of early stage prostate cancer; however, the benefit of early detection on patient outcome has not been proven and is the subject of ongoing clinical trials.[4-7, 13-15, 18, 19]

PSA testing can have significant value in detecting metastatic or persistent disease in patients following surgical or medical treatment of prostate cancer. Persistent elevation of PSA following treatment, or an increase in a post-treatment PSA level is indicative of recurrent or residual disease. PSA testing is widely accepted as an adjunctive test in the management of prostate cancer patients.[3-7]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Total PSA assay is a two-step immunoassay to determine the presence of Total PSA (both Free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and anti-PSA coated paramagnetic microparticles are combined to create a reaction mixture. The PSA present in the sample binds to the anti-PSA coated microparticles.
2. After washing, anti-PSA acridinium-labeled conjugate is added. Pre-Trigger and Trigger Solutions are then added to the reaction mixture.
3. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of Total PSA in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT Total PSA 7K70

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	7K70-25	7K70-20	7K70-35	7K70-30
Σ	100	400	500	2000
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL	4 x 26.3 mL

MICROPARTICLES Anti-PSA (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine) stabilizer. Preservative: antimicrobial agents.

CONJUGATE Anti-PSA (mouse, monoclonal) acridinium-labeled Conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 10 ng/mL. Preservative: antimicrobial agents.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

NOTE: Bottle and volume varies based on order.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[20-23]

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.
  - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage. Store in upright position.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT Total PSA assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

ARCHITECT Free PSA

REF 7K71-25
REF 7K71-20

en
Free PSA
7K71
G27497R06
B7K710

Read Highlighted Changes: Revised May 2019.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: The concentration of Free PSA in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the Free PSA assay used. Values obtained with different assay methods cannot be used interchangeably.

NAME

ARCHITECT Free PSA (Prostate Specific Antigen)

INTENDED USE

The ARCHITECT Free PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Free Prostate Specific Antigen (PSA) in human serum. The ARCHITECT Free PSA assay is intended to be used in conjunction with the ARCHITECT Total PSA assay in men aged 50 years or older with Total PSA values between 4 and 10 ng/mL and DRE non-suspicious for cancer to determine the % Free PSA value. The ARCHITECT % Free PSA value can be used as an aid in discriminating between prostate cancer and benign disease.

SUMMARY AND EXPLANATION OF THE TEST

Prostate specific antigen (PSA), a member of the human kallikrein gene family, is a serine protease with chymotrypsin-like activity.[1-3] The mature form of PSA is a single chain glycoprotein of 237 amino acids containing 7-8% carbohydrate as a single N-linked oligosaccharide side chain. PSA has a molecular weight of approximately 30,000 daltons.[1, 3, 4]

The major site of PSA production is the glandular epithelium of the prostate. PSA produced by the prostate is secreted into the seminal fluid in high concentrations. PSA is also present in urine and serum.[3] The function of PSA is the proteolytic cleavage of gel forming proteins in the seminal fluid resulting in liquefaction of the seminal gel and increased sperm mobility.[3, 5] Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. Increasing levels of PSA are associated with prostatic pathology; including prostatitis, benign prostatic hyperplasia (BPH), and cancer of the prostate.[6-9]

PSA occurs in three major forms in blood. The major immunodetectable form is PSA complexed with the serine protease inhibitor, alpha-1-antichymotrypsin (PSA-ACT). Uncomplexed, or Free PSA, is the other immunodetectable form of PSA in serum. The majority of Free PSA in serum appears to be an inactive form that cannot complex with protease inhibitors and may be either a PSA zymogen or an enzymatically-inactive, cleaved form of PSA. A third form of PSA, a complex with alpha-2-macroglobulin (AMG), is not detectable with current immunoassays for PSA due to the engulfment and subsequent masking of PSA epitopes by the alpha-2-macroglobulin molecule.[2, 3, 10]

Immunoassays have been designed to detect Free PSA, PSA-ACT complex, and Total PSA (immunodetectable forms: e.g., Free PSA and PSA-ACT).[10-12] Using these types of assays, the proportion of Free PSA in the serum was found to be significantly higher in patients with BPH than in patients with prostate cancer ($p < 0.00001$).[12] The proportion, or percent, of Free PSA determined by comparing the concentration of Free PSA to the concentration of Total PSA has been proposed as a way to improve the discrimination between BPH and prostate cancer, especially in those men with intermediate levels of total serum PSA.[10, 12-17]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Free PSA assay is a two step immunoassay to determine the presence of Free PSA in human serum, using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and anti-Free PSA coated paramagnetic microparticles are combined. The Free PSA present in the sample binds to the anti-Free PSA coated microparticles.
2. After washing, anti-PSA acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of Free PSA in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT Free PSA 7K71

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	7K71-25	7K71-20
Σ	100	400
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL

MICROPARTICLES Anti-Free PSA (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine) stabilizer. Preservative: antimicrobial agents.

CONJUGATE Anti-PSA (mouse, monoclonal) acridinium-labeled Conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 10 ng/mL. Preservative: antimicrobial agents.

Other Reagents

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

NOTE: Bottle and volume varies based on order.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

ARCHITECT CA 19-9XR

REF 2K91-24
REF 2K91-32
REF 2K91-39

CA 19-9XR
2K91
613-031 11/16/R03
B2K9Y0

Read Highlighted Changes: Revised November 2016.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: The Abbott ARCHITECT CA 19-9XR CMIA assay utilizes an antibody/antigen system based on the 1116-NS-19-9 antibody. The unique reagent formulation employed in the ARCHITECT CA 19-9XR assay may return elevated concentrations when compared to other methods for samples expressing high levels of 1116-NS-19-9 reactive determinants.[1, 2] Additionally, there is no internationally recognized standard for CA 19-9, which can contribute to differences between assay methods. The ARCHITECT CA 19-9XR assay is standardized to a reference standard prepared by Fujirebio Diagnostics, Inc. Performance characteristics of the Abbott ARCHITECT CA 19-9XR assay are NOT transferable to other diagnostic kits.

The concentration of 1116-NS-19-9 reactive determinants obtained with different assay methods cannot be used interchangeably due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 19-9 assay used. If, in the course of monitoring a patient, the assay method used for determining serial 1116-NS-19-9 reactive determinant levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

WARNING: 1116-NS-19-9 reactive determinants are shed naturally in saliva and other body fluids.[3] Contamination of the samples or the ARCHITECT iSystem disposables with saliva or aerosols (e.g., as a result of sneezing) may cause falsely elevated CA 19-9 assay values. It is recommended that all elevated values be reviewed and testing repeated as appropriate. Gloves should always be worn when handling samples, sample cups, reaction vessels, and septums. Face masks are also recommended.

NAME

ARCHITECT CA 19-9XR

INTENDED USE

The ARCHITECT CA 19-9XR assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma on the ARCHITECT iSystem. The ARCHITECT CA 19-9XR assay is to be used as an aid in the management of pancreatic cancer patients in conjunction with other clinical methods.

SUMMARY AND EXPLANATION OF THE TEST

The ARCHITECT CA 19-9XR assay detects a tumor-associated antigen, which occurs in tissue as a monosialoganglioside and in serum as a high molecular weight, carbohydrate-rich glycoprotein known as a mucin.[4-7]

The ARCHITECT CA 19-9XR assay is based upon a monoclonal antibody, 1116-NS-19-9, which reacts with a carbohydrate antigenic determinant expressed on the circulating antigen.[4-6]

The results of published research studies[8-14] indicate that the CA 19-9 assay value is frequently elevated in the serum of subjects with various gastrointestinal conditions, such as pancreatic, colorectal, gastric, and hepatic carcinomas. No data exist to support the use of CA 19-9 in screening for malignancies.[15, 16] The role of CA 19-9 is to be used as an adjunct with other diagnostic information in the management of patients with pancreatic cancer.[15] Increased serum CA 19-9 assay values have also been observed in patients with metastases and in nonmalignant conditions such as hepatitis, cirrhosis, pancreatitis, and other gastrointestinal disease.[8-11, 17-20] Elevated levels have also been seen in cystic fibrosis.[21-24] Research studies demonstrate that CA 19-9 assay values may have utility in monitoring subjects with the above-mentioned diagnosed gastrointestinal malignancies.[25-28] It has been shown that a persistent elevation in CA 19-9 assay value following treatment may be indicative of occult metastatic and/or residual disease. A persistently rising CA 19-9 assay value may be associated with progressive malignant disease and poor therapeutic response. A declining CA 19-9 assay value may be indicative of a favorable prognosis and a good response to treatment.[29-35]

Testing for 1116-NS-19-9 reactive determinants must not be used as a screening procedure for malignancy. 1116-NS-19-9 reactive determinants are present as a normal constituent in serum and plasma of individuals without gastrointestinal carcinomas or having certain aforementioned non-cancer related conditions.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CA 19-9XR assay is a two-step immunoassay for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and 1116-NS-19-9 coated paramagnetic microparticles are combined. The 1116-NS-19-9 reactive determinants present in the sample bind to the 1116-NS-19-9 coated microparticles.
2. After washing, 1116-NS-19-9 acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of 1116-NS-19-9 reactive determinants in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

REAGENTS

Kit Contents

ARCHITECT CA 19-9XR 2K91

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	2K91-32	2K91-24	2K91-39
Σ	100	400	500
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL

MICROPARTICLES 1116-NS-19-9 (mouse, monoclonal) coated microparticles in citrate buffer with protein (bovine) stabilizer. Minimum concentration: 0.09% solids. Preservatives: sodium azide and ProClin 300.

CONJUGATE 1116-NS-19-9 (mouse, monoclonal) acridinium-labeled conjugate in phosphate buffer with protein (bovine) stabilizer. Minimum concentration: 0.5 µg/mL. Preservatives: sodium azide and ProClin 300.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[36-39]

The following warnings and precautions apply to: MICROPARTICLES	
	
WARNING	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: CONJUGATE	
	
DANGER	Contains polyethylene glycol octylphenyl ether, methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P280	Wear protective gloves / protective clothing / eye protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor / physician.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- 1116-NS-19-9 reactive determinants are shed naturally in saliva and other body fluids.[3] Contamination of the samples or the ARCHITECT iSystem disposables with saliva or aerosols (e.g., as a result of sneezing) may cause falsely elevated CA 19-9 assay values. It is recommended that all elevated values be reviewed and testing repeated as appropriate. Gloves should always be worn when handling samples, sample cups, reaction vessels, and septums. Face masks are also recommended.
- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.

ARCHITECT CA 15-3

REF 2K44-21
REF 2K44-27
REF 2K44-37

en
CA 15-3
2K44
614-001_R02
B2K4V0

Read Highlighted Changes: Revised August 2018.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: CA 15-3 assay values obtained with different assay methods cannot be used interchangeably due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 15-3 assay used. If, in the course of monitoring a patient, the assay method used for determining serial CA 15-3 levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

NAME

ARCHITECT CA 15-3

INTENDED USE

The ARCHITECT CA 15-3 assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of DF3 defined antigen in human serum and plasma on the ARCHITECT iSystem.

The ARCHITECT CA 15-3 assay is to be used as an aid in the management of Stage II and III breast cancer patients. Serial testing for patient CA 15-3 assay values should be used in conjunction with other clinical methods for monitoring breast cancer.

SUMMARY AND EXPLANATION OF THE TEST

The ARCHITECT CA 15-3 assay values are defined by using the 115D8 and DF3 monoclonal antibodies.[1, 2] Monoclonal antibody 115D8, raised against human milk-fat globule membranes, and monoclonal antibody DF3, raised against a membrane enriched fraction of metastatic human breast carcinoma, react with epitopes expressed by a family of high molecular weight glycoproteins designated as polymorphic epithelial mucins (PEMs).[3-6]

Research studies have indicated that CA 15-3 assay values are frequently elevated in patients with breast cancer.[7-17] These studies have suggested that the CA 15-3 assay may be of clinical value for monitoring the response of patients undergoing therapy because increasing and decreasing values correlated with disease progression and regression, respectively.[1, 7, 10, 15-16] Additional published studies have suggested that increasing CA 15-3 assay values in patients at risk for breast cancer recurrence after primary therapy may be indicative of recurrent disease before it can be detected clinically.[10, 15, 16, 19]

Elevations of CA 15-3 assay values have been reported in individuals with nonmalignant conditions such as cirrhosis, hepatitis, autoimmune disorders, and benign diseases of the ovary and breast.[7, 8] Non-mammary malignancies in which elevated CA 15-3 assay values have been reported include lung, colon, pancreatic, primary liver, ovarian, cervical, and endometrial.[7, 20] CA 15-3 assay values are not elevated in most normal individuals.[7]

The CA 15-3 assay is not recommended as a screening procedure to detect cancer in the general population; however, use of the CA 15-3 assay as an aid in the management of breast cancer patients has been reported.[7-19]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CA 15-3 assay is a two-step immunoassay for the quantitative determination of DF3 defined antigens in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, wash buffer and 115D8 coated paramagnetic microparticles are combined. The DF3 defined antigen present in the sample binds to the 115D8 coated microparticles.
2. After washing, DF3 acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of DF3 defined antigen in the sample and the RLUs detected by the ARCHITECT iSystem optics.

This assay is unique in that the calibrators are supplied prediluted. The ARCHITECT System dilutes all controls and specimens by the same final dilution factor as the prediluted calibrators during the course of the assay.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT CA 15-3 2K44

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	2K44-27	2K44-21	2K44-37
Σ	100	400	500
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL

MICROPARTICLES 115D8 (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.09% solids. Preservatives: sodium azide and ProClin 300.

CONJUGATE DF3 (mouse, monoclonal) acridinium-labeled conjugate in phosphate buffer with protein (bovine) stabilizer. Minimum concentration: 0.05 µg/mL. Preservatives: sodium azide and ProClin 300.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

ARCHITECT CA 125 II

REF 2K45-24
REF 2K45-29
REF 2K45-39

en
CA 125 II
2K45
615-001_R02
B2K4F0

Read Highlighted Changes: Revised August 2018.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

WARNING: CA 125 assay values obtained with different assay methods cannot be used interchangeably due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 125 assay used. If, in the course of monitoring a patient, the assay method used for determining serial CA 125 levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

NAME

ARCHITECT CA 125 II

INTENDED USE

The ARCHITECT CA 125 II assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of OC 125 defined antigen in human serum and plasma on the ARCHITECT iSystem.

The ARCHITECT CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 II assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

SUMMARY AND EXPLANATION OF THE TEST

CA 125 II assay values are defined by using the OC 125 monoclonal antibody. OC 125 was generated through the hybridization of mouse myeloma cells to spleen cells from a mouse immunized with a human serous cystadenocarcinoma cell line called OVCA 433.[1] ARCHITECT CA 125 II is a second-generation assay for the detection of OC 125 defined antigen. The assay utilizes the OC 125 monoclonal antibody, as the capture antibody coated onto paramagnetic microparticles that bind molecules containing OC 125 defined antigen. These defined antigens are quantified using acridinium-labeled M11 antibody. The OC 125 monoclonal antibody is reactive with repeating OC 125 defined antigen expressed by a high percentage of nonmucinous ovarian carcinomas (serous, endometrioid, clear cell, and undifferentiated histologies) and epithelial ovarian carcinoma cell lines.[1, 2] OC 125 defined antigens were originally detected in normal peritoneal, pleural and pericardial tissues of both fetus and adult. In the fetus, OC 125 defined antigens have been localized in amniotic and umbilical epithelial and Müllerian epithelial tissues. In the adult, localization has been identified in endocervical and endometrial tissues and ovarian inclusion cysts and papillary excrescences. However, OC 125 defined antigens were not detected in fetal ovarian tissue or other normal adult ovarian tissues or benign mucinous ovarian tumors.[3] In serum, the OC 125 defined antigens are associated with high molecular weight glycoproteins heterogeneous in size and charge. The structure of the CA 125 molecule, including closely situated repeating epitopes for OC 125 and M11 antibodies has been proposed.[4]

Serum CA 125 II assay values are useful for monitoring the course of disease in patients with invasive epithelial ovarian cancer.[5] In a review of nine published studies, the overall correlation reported between CA 125 serum levels and the course of the disease was 87%.[6] Persistently rising CA 125 assay values may be associated with malignant disease and poor response to therapy, whereas decreasing CA 125 assay values may indicate a favorable response to therapy.[6-14]

A second-look, exploratory laparotomy may have been performed previously to assess response to therapy. The benefit has recently come into question because of high morbidity and low sensitivity in detecting residual or recurrent carcinoma.[15] In women with primary epithelial ovarian carcinoma who had undergone first-line therapy and were candidates for diagnostic second-look procedures, a CA 125 assay value greater than or equal to 35 U/mL was found to be indicative of the presence of residual tumor.[6, 9, 11, 13] However, a CA 125 assay value below 35 U/mL does not indicate the absence of residual ovarian cancer because patients with histopathologic evidence of ovarian carcinoma may have CA 125 assay values within the range of normal individuals.[7, 8]

Elevations of CA 125 assay values have been reported in approximately 1-2% of healthy individuals,[6, 7] and in individuals with nonmalignant conditions such as cirrhosis,[16, 17] hepatitis,[17, 18] endometriosis,[19-24] first trimester pregnancy,[25-27] ovarian cysts,[3, 28] and pelvic inflammatory disease.[10, 25] Elevations of CA 125 assay values during the menstrual cycle have also been reported.[23, 29] Non-ovarian malignancies in which CA 125 assay values have been reported include endocervical,[30] liver,[18] pancreatic,[18, 31] lung,[18] colon,[18, 31] stomach,[18, 31] biliary tract,[18, 31] uterine,[17] fallopian tube,[30] breast,[18] and endometrial carcinomas.[30, 32] The CA 125 assay is not recommended as a screening procedure to detect cancer in the general population; however, the use of CA 125 assay values as an aid in the management of ovarian cancer patients has been reported.[7-14]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CA 125 II assay is a two-step immunoassay for the quantitative determination of OC 125 defined antigen in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and OC 125 coated paramagnetic microparticles are combined. The OC 125 defined antigen present in the sample binds to the OC 125 coated microparticles.
2. After washing, M11 acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of OC 125 defined antigen in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT CA 125 II 2K45

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	2K45-29	2K45-24	2K45-39
Σ	100	400	500
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL

MICROPARTICLES anti-CA 125 (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizers. Minimum concentration: 0.09% solids. Preservatives: Sodium Azide and ProClin 300.

CONJUGATE anti-CA 125 (mouse, monoclonal) acridinium-labeled conjugate in phosphate buffer with protein (bovine) stabilizers. Minimum concentration: 0.075 µg/mL. Preservatives: Sodium Azide and ProClin 300.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[33-36]

The following warnings and precautions apply to: MICROPARTICLES and CONJUGATE

WARNING	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
  - **To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.**
  - Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage. Store in upright position.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If any reagent bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

ธ.ก.ส. สาขาถนนโพธิ์ 4
481 ถ.สาธุประดิษ-รังสิต
แขวงสามเสนใน เขตพญาไท
กรุงเทพมหานคร 10320
โทร. 02-5398733

ข้อกำหนดและเงื่อนไข

1. นำสมุดเงินฝากมาธนาคารทุกครั้งที่ฝากหรือถอน
2. ธนาคารจะบันทึกดอกเบี้ยให้ในวันเสาร์สุดท้ายเดือนกันยายนและมีนาคมของทุกปี
3. ยอดเงินที่ปรากฏในสมุดเงินฝากจะถือว่าถูกต้องเมื่อได้รับการตรวจสอบยอดตรงกับบัญชีเงินฝากของธนาคารแล้ว กรณียอดเงินคงเหลือเป็นศูนย์ธนาคารจะปิดบัญชีทันที
4. การเปลี่ยนชื่อ ชื่อสกุล ที่อยู่ ผู้ฝากต้องแจ้งให้ธนาคารทราบ กรณีสมุดเงินฝากหาย ผู้ฝากต้องแจ้งความต่อเจ้าหน้าที่ตำรวจ และแจ้งให้ธนาคารทราบโดยเร็ว
5. ในกรณีที่บัญชีขาดการติดต่อ และยอดคงเหลือในบัญชีต่ำกว่าที่กำหนด ธนาคารจะปิดบัญชี และ/หรือคิดค่าธรรมเนียมรักษาบัญชีตามหลักเกณฑ์ที่ธนาคารกำหนด

เพื่อประสานงานเกี่ยวกับการรับของประกวดราคา,ยื่นซองสอบราคา,ประกวดราคา,เสนอราคา,ลงนามหรือแก้ไขใบเสนอราคา,ลงนามในใบสั่งซื้อ,ลงนามในสัญญาซื้อขาย,ลงนามในสัญญาจะซื้อจะขาย,ลงนามในข้อตกลงซื้อขาย,ลงนามในสัญญาเช่า,รับใบสั่งซื้อ,ใบส่งของ,เก็บเงินค่าสินค้า พร้อมทั้งลงนามรับรองเอกสาร, แก้ไขหรือเพิ่มเติมในเอกสารต่างๆ กับ จังหวัดนครปฐม เท่านั้น

รหัสสาขา 0058 Branch Code
บัญชีเลขที่ 010582227554 Account No.
ชื่อสาขา สาขาจตุจักร Branch Name
รหัสโครงการ Project Code

ชื่อบัญชี
Account Name
บริษัท ไอเมด ลาบอราทอรี่ จำกัด

2001 – บัญชีเงินฝากออมทรัพย์ (ใช้สมุดคู่ฝาก)

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ธนาคารเพื่อการเกษตรและสหกรณ์การเกษตร
BANK FOR AGRICULTURE AND AGRICULTURAL CO-OPERATIVES

เล่มที่ 000151185897

Authorized Signature

16-01/60

i-MED LABORATORIES COMPANY LIMITED

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