Alinity i

Syphilis TP Reagent Kit

en
Syphilis
07P60
G71147R01
B7P600

Created October 2016.

REF 07P6022
REF 07P6032

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME

Alinity i Syphilis TP Reagent Kit (also referred to as Syphilis)

INTENDED USE

The Alinity i Syphilis TP assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibodies to *Treponema pallidum* (TP) in human serum and plasma, including specimens collected postmortem (non-heart-beating) on the Alinity i analyzer.

The Alinity i Syphilis TP assay is intended to be used as an aid in the diagnosis of Syphilis infection and as a screening test to prevent transmission of *Treponema pallidum* to recipients of blood, blood components, cells, tissue and organs.

SUMMARY AND EXPLANATION OF THE TEST

Syphilis is caused by infection with the bacterium TP[1] which can be transmitted congenitally or by sexual contact. The disease can evolve into a latent phase in which syphilis is clinically inapparent. Serological tests (nontreponemal and treponemal specific), in addition to patients' clinical history, are currently the primary methods for the diagnosis and management of syphilis.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

This assay is a two-step immunoassay for the qualitative detection of antibody to TP in human serum or plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, and recombinant TP antigen (TpN15, TpN17, and TpN47) coated paramagnetic microparticles, and assay diluent are combined and incubated. The Anti-TP antibodies present in the sample bind to the TP coated microparticles. The mixture is washed. Anti-human IgG and IgM acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of anti-TP antibodies in the sample and the RLUs detected by the system optics.

The presence or absence of anti-TP antibodies in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity i Syphilis TP Reagent Kit 07P60

NOTE: Some kit sizes are not available in all countries. Please contact your local distributor.

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	07P6022	07P6032
Tests per cartridge	100	600
Number of cartridges per kit	2	2
Tests per kit	200	1200
MICROPARTICLES	4.2 mL	16.8 mL
CONJUGATE	4.2 mL	16.3 mL
ASSAY DILUENT	5.9 mL	28.7 mL

MICROPARTICLES TP (*E.coli*, recombinant) antigen coated microparticles in HEPES buffer with detergent. Minimum concentration: 0.08 % solids. Preservatives: sodium azide and other antimicrobial agents.

CONJUGATE Murine anti-IgG/anti-IgM acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: (anti-IgG) 26.6 ng/mL / (anti-IgM) 1.34 ng/mL. Preservatives: sodium azide and other antimicrobial agents.

ASSAY DILUENT Syphilis TP Assay Diluent containing MES buffer with detergent. Preservatives: ProClin 950 and other 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.[2-5]

The following warnings and precautions apply to: ASSAY DILUENT	
	
WARNING	Contains Polyethylene glycol octylphenyl ether (Triton X-100) and Methylisothiazolone.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.

Abbott

Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.
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: MICROPARTICLES and CONJUGATE

WARNING	Contains Polyethylene glycol octylphenyl ether (Triton X-405) and Sodium azide.
H319	Causes serious eye irritation.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P280	Wear protective gloves / protective clothing / eye protection.
P264	Wash hands thoroughly after handling.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.
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 Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.
  - Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.
- After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright during storage, discard the cartridge. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity i Syphilis TP assay file must be installed on the Alinity i analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator

Specimen Types	Collection Tubes
Plasma	Potassium EDTA
	Lithium heparin
	Sodium heparin
	Sodium citrate
	CPD

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.
- For cadaveric donors, serum and plasma may be used; follow general standards and/or regulations for collection, storage and handling.
- Performance has been established for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating) that have been collected up to 21.5 hours after death. Performance was established using 50 spiked and 50 non-spiked cadaveric blood specimens.[6]
- Testing of cadaveric blood specimens from patients with plasma dilution due to transfusions of > 2000 mL of blood or colloids within 48 hours, or > 2000 mL of crystalloids within 1 hour (or any combination thereof) prior to collection of the specimens have not been validated.
- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross-contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter
- they require repeat testing.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Prepare cadaveric blood specimens as follows:

- After initial centrifugation, recentrifuge specimens as described below.
- If specimens are not processed directly after initial centrifugation, it is recommended to remove the supernatant from the clot, red blood cells or separator gel until further processing.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge at a minimum of 100 000 g-minutes.
- Examples of acceptable time and force ranges that meet this criterion are listed in the table below.

  Centrifugation time using alternate RCF values can be calculated using the following formula:

$$\text{Minimum Centrifugation time (minutes)} = \frac{100\,000 \text{ g-minutes}}{\text{RCF}}$$

Recentrifugation Time (Minutes)	RCF (x g)	g-Minutes
10	10 000	100 000
20	5000	100 000
40	2500	100 000

$$RCF = 1.12 \times r_{max} \, (rpm/1000)^2$$

RCF -	The relative centrifugal force generated during centrifugation.
rpm -	The revolutions per minute of the rotor on which the specimens are being spun (usually the digital readout on the centrifuge will indicate the rpm).
Centrifugation Time -	The time should be measured from the time the rotor reaches the required RCF or rpm to the time it begins decelerating.
r_{max} -	Radius of the rotor in millimeters. NOTE: If custom tube adapters (i.e., adapters not defined by the centrifuge manufacturer) are used, then the radius (rmax) should be manually measured in millimeters and the RCF calculated.
g-minutes -	The unit of measure for the product of RCF (× g) and centrifugation time (minutes).

- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum	Room temperature	72 hours	If testing will be delayed, serum should be removed from the clot, red blood cells, or separator gel.
	2 to 8°C	7 days	If testing will be delayed, serum should be removed from the clot, red blood cells, or separator gel.

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Plasma	Room temperature	72 hours	If testing will be delayed, plasma should be removed from the clot, red blood cells, or separator gel.
	2 to 8°C	30 days	If testing will be delayed, plasma should be removed from the clot, red blood cells, or separator gel.
Cadaveric	Room temperature (15 to 30°C)	1 day	If specimens are not processed directly after initial centrifugation, it is recommended to remove the supernatant from the clot, red blood cells or separator gel until further processing.
	2 to 8°C	7 days	If specimens are not processed directly after initial centrifugation, it is recommended to remove the supernatant from the clot, red blood cells or separator gel until further processing.

Remove serum or plasma from the clot, serum separator, or red blood cells if stored longer than the maximum 2 to 8°C storage time and store frozen.

Avoid multiple freeze/thaw cycles.

No qualitative differences were observed for cadaveric blood specimens (nonreactive or spiked reactive) when subjected to up to 3 freeze/thaw cycles.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

07P60 Alinity i Syphilis TP Reagent Kit

Materials Required but not Provided

- Alinity i Syphilis TP assay file
- 07P6001 Alinity i Syphilis TP Calibrator
- 07P6010 Alinity i Syphilis TP Controls or other control material
- 06P1160 Alinity Trigger Solution
- 06P1265 Alinity Pre-Trigger Solution
- 06P1368 Alinity i-series Concentrated Wash Buffer

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
  - Priority:
    - Sample volume for first test: 80 µL
    - Sample volume for each additional test from same sample cup: 30 µL
  - ≤ 3 hours on the reagent and sample manager:
    - Sample volume for first test: 150 µL
    - Sample volume for each additional test from same sample cup: 30 µL
  - > 3 hours on the reagent and sample manager:
    - Replace with a fresh aliquot of sample.
- Refer to the Alinity i Syphilis TP calibrator package insert and Alinity i Syphilis TP control package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Samples cannot be diluted for the Alinity i Syphilis TP assay.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Each assay control must be tested to evaluate the assay calibration.

Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.
- Daily quality control results are outside of statistically-based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert.
  - If statistically-based quality control limits are not available then the calibration should not exceed a 30-day limit for recalibration frequency.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

The recommended control requirement for the Alinity i Syphilis TP assay is that a single sample of each control level be tested once every 24 hours each day of use.

Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

To establish statistically-based control limits, each laboratory should establish its own concentration target and ranges for new control lots at each clinically relevant control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days and using the reported results to establish the expected average (target) and variability about this average (range) for the laboratory. Sources of variation that should be included in this study in order to be representative of future system performance include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots

- Multiple processing modules (if applicable)
- Data points collected at different times of the day

Refer to published guidelines for information or general control recommendation, for example Clinical and Laboratory Standards Institute (CLSI) Document C24-A3 or other published guidelines, for general quality control recommendations.[7]

- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[8]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity i analyzer calculates results for the Alinity i Syphilis TP assay using the ratio of the sample RLU to the cutoff RLU (S/CO) for each specimen and control.

Cutoff RLU = Calibrator 1 Mean RLU x 0.20

The cutoff RLU is stored for each reagent lot calibration.

S/CO = Sample RLU/Cutoff RLU

Interpretation of Results

The cutoff is 1.00 S/CO.

S/CO	Interpretation
< 1.00	Nonreactive
≥ 1.00	Reactive

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- False positive results can be expected with any test kit. The proportion of these falsely reactive specimens is dependent upon the specificity of the test kit, specimen integrity, and the characteristics of the local population being screened.
- If the Alinity i Syphilis TP results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- No diagnostic test provides absolute assurance that a sample does not contain low levels of antibodies to TP, such as those present at a very early stage of infection. Therefore, a negative result at any time does not preclude the possibility of exposure to infection with syphilis. Additional information may be required for diagnosis.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity i analyzer and the ARCHITECT i System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity i analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 3 lots of the Alinity i Syphilis TP Reagent Kit, 3 lots of the Alinity i Syphilis TP Calibrator, 3 lots of the Alinity i Syphilis TP Controls, and 1 instrument. Two controls and 5 recalcified human plasma panels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[9]

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	Mean (S/CO)	SD	%CV	SD (Range[b])	%CV (Range[b])
Negative Control	359	0.03	0.003	9.9	0.004 (0.002-0.005)	12.1 (7.7-14.6)
Positive Control	355[c]	2.65	0.067	2.5	0.117 (0.109-0.127)	4.4 (4.2-4.7)
Panel A	352	0.51	0.014	2.8	0.022 (0.021-0.023)	4.3 (3.9-4.6)
Panel B	360	1.18	0.031	2.6	0.045 (0.043-0.048)	3.9 (3.7-4.1)
Panel C	352	3.38	0.149	4.4	0.180 (0.112-0.267)	5.3 (3.3-8.1)
Panel D	360	6.31	0.123	1.9	0.200 (0.189-0.221)	3.2 (3.0-3.4)
Panel E	360	0.08	0.007	8.7	0.007 (0.005-0.010)	9.5 (6.7-12.7)

[a] Includes within-run, between-run, and between-day variability.

[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

[c] An outlying run was observed. Based on guidance from CLSI EP05-A2, a replacement run was performed and the results are shown in the table above. Without the replacement run, the within-run (repeatability) %CV was 5.6% and the within-laboratory precision (total) %CV was 6.4%.

Specificity

A total of 5119 negative blood donor specimens and 531 hospitalized negative patient specimens were tested on the Alinity i Syphilis TP assay. Testing was performed using 3 Alinity i Syphilis TP Reagent Kits and 1 lot each of Alinity i Syphilis TP Calibrator and Alinity i Syphilis TP Controls on 4 Alinity i analyzers.

A total of 3 specimens were falsely reactive for the blood donor specimens based on the initial result. None of the RR was confirmed positive by supplemental testing. There were no specimens that were falsely reactive for the hospitalized patient specimens.

Category	n	Alinity i Syphilis TP IR (% of Total)[a]	Alinity i Syphilis TP RR (% of Total)	Alinity i Syphilis TP Specificity[a] (95% CI)	Commercially-Available Syphilis Assay Specificity[a] (95% CI)
Blood Donors Overall	5119	3 (0.06)	2 (0.04)	99.94% (5116/5119) (99.83% - 99.99%)	99.98% (5349/5350[b]) (99.90% - 100.00%)
Blood Donors Serum	2424	2 (0.08)	1 (0.04)	99.92% (2422/2424) (99.70% - 99.99%)	99.96% (2618/2619[b]) (99.79% - 100.00%)
Blood Donors Plasma	2695	1 (0.04)	1 (0.04)	99.96% (2694/2695) (99.79% - 100.00%)	100.00% (2731/2731[b]) (99.87% - 100.00%)
Hospitalized Patients	531	0 (0.00)	0 (0.00)	100.00% (531/531[b]) (99.31% - 100.00%)	100.00% (523/523) (99.30% - 100.00%)

IR = Initially Reactive, RR = Repeatedly Reactive, CI = Confidence Interval

[a] Specificity was calculated based on initially reactive specimens.

[b] The additional specimens tested were not initially reactive.

Sensitivity

The Alinity i Syphilis TP assay demonstrated a sensitivity of 100.00% in a study testing samples that were confirmed as true positive. 412 syphilis-positive specimens were tested, split across 3 Alinity i Syphilis TP Reagent Kits and 1 lot each of Alinity i Syphilis TP Calibrator and Alinity i Syphilis TP Controls on 2 Alinity i analyzers. The samples were tested in singlicate.

The same 412 syphilis-positive specimens were also tested using a commercially-available Syphilis assay and demonstrated a sensitivity of 100.00%. The specimens were tested using 1 lot of commercially-available Syphilis reagent kit, calibrators, and controls on 1 instrument. The samples were tested in singlicate.

Interference

This study was performed on the ARCHITECT i System.

Potentially Interfering Endogenous Substances

Potential interference was < 0.40 S/CO difference on negative specimens and < 20% S/CO difference on reactive samples with the following interferent levels.

Potentially Interfering Substance	Interferent Level
Triglycerides	≤ 3000 mg/dL
Bilirubin	≤ 20 mg/dL
Protein	≤ 12 g/dL
Hemoglobin	≤ 500 mg/dL

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Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
INVERSIONS PERFORMED	Inversions Performed
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRODUCT OF GERMANY	Product of Germany
REF	List Number
SN	Serial number

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CE

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

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