ARCHITECT Syphilis TP

REF 8D06-32
REF 8D06-42

en
Syphilis TP
8D06
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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.

NAME

ARCHITECT Syphilis TP

INTENDED USE

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

The ARCHITECT Syphilis TP assay is a two-step immunoassay for the qualitative detection of antibody to TP in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, microparticles coated with recombinant TP antigens (TpN15, TpN17 and TpN47) and Assay Diluent are combined. Anti-TP antibodies present in the sample bind to the TP coated microparticles.
2. After washing, acridinium-labeled anti-human IgG and IgM 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 anti-TP antibodies in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of anti-TP antibodies in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from a previous ARCHITECT Syphilis TP calibration. If the chemiluminescent signal in the specimen is greater than or equal to the cutoff signal, the specimen is considered reactive for anti-TP.

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

REAGENTS

Kit Contents

ARCHITECT Syphilis TP 8D06

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

REF	8D06-32	8D06-42
Σ	100	500
MICROPARTICLES	1 x 4.1 mL	1 x 16.3 mL
CONJUGATE	1 x 5.9 mL	1 x 26.3 mL
ASSAY DILUENT	1 x 6.3 mL	1 x 34.1 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 agent.

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.

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: MICROPARTICLES / 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	
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
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.

The following warnings and precautions apply to: **ASSAY DILUENT**

WARNING:	Contains Polyethylene glycol octylphenyl ether (Triton X-100) and Methylisothiazolone.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
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.
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.

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.
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG/IgM will result in a neutralized conjugate.

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 Syphilis TP 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.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Verified specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum
	Serum separator tubes
Human plasma	Potassium EDTA
	Lithium heparin
	Sodium heparin
	Sodium citrate
	CPD

- Other specimen collection tube types have not been tested with this assay.
- Performance has not been established for the use of body fluids other than human serum or plasma.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.
- Performance has been established for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating), for details refer to section **Testing of Cadaveric Blood Specimens**.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - grossly hemolyzed (> 500 mg/dL hemoglobin)
  - 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.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if
  - they contain fibrin, red blood cells, or other particulate matter,
  - they require repeat testing, or
  - they were frozen and thawed.

  Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum	Room temperature	≤ 72 hours
	2-8°C	≤ 7 days
Plasma	Room temperature	≤ 72 hours
	2-8°C	≤ 30 days

If testing will be delayed, serum or plasma should be removed from the clot, red blood cells, or separator gel.

Avoid multiple 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.
- Do not exceed the storage limitations listed above.

Testing of Cadaveric Blood Specimens

- 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. [7]
- 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.
- Follow general standards and/or regulations for collection, storage and handling.
- Follow the tube manufacturer's processing instructions for serum or plasma collection tubes. After initial centrifugation, transfer the supernatant to a centrifuge tube and centrifuge at 10,000 RCF (Relative Centrifugal Force) for 10 minutes. 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.
- Cadaveric blood specimens can be stored for up to 7 days at 2-8°C or up to 1 day at 15-30°C following collection.
- No qualitative differences were observed for cadaveric blood specimens (nonreactive or spiked reactive) when subjected to up to 3 freeze/thaw cycles. However, multiple freeze/thaw cycles should be avoided.

PROCEDURE

Materials Provided

8D06 ARCHITECT Syphilis TP Reagent Kit

Materials Required but not Provided

- ARCHITECT Syphilis TP Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 8D06-04 ARCHITECT Syphilis TP Calibrator
- 8D06-13 ARCHITECT Syphilis TP Controls
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- 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. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, discard the cap and place a septum on the bottle. For instructions on placing septums on bottles refer to the **Reagent Handling** section of this package insert.
- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. 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 board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 30 µL
  - > 3 hours on board: Additional sample volume required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare ARCHITECT Syphilis TP Calibrator and Controls.
  - Mix calibrator(s) and controls by gentle inversion before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 5 drops

    for each control: 5 drops
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures

Specimens cannot be diluted for the ARCHITECT Syphilis TP assay.

Calibration

- Test Calibrator 1 in replicates of three. The calibrator should be priority loaded.

  A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
- Once an ARCHITECT Syphilis TP 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 or
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

The recommended control requirement for the ARCHITECT Syphilis TP assay is that a single sample of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

Ensure that assay control values are within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

RESULTS

The ARCHITECT iSystem calculates the cutoff (CO) using the mean chemiluminescent signal (RLU) from three replicates of the Calibrator 1 and stores the result.

Calculation

The ARCHITECT Syphilis TP assay calculates a result based on a cutoff determined by the following calculation.

- Cutoff (CO) = Calibrator 1 Mean RLU x 0.20
- S/CO = Sample RLU / Cutoff RLU
- The cutoff RLU is stored for each reagent lot calibration.

Interpretation of Results

- Specimens with S/CO values < 1.00 are considered nonreactive by the ARCHITECT Syphilis TP assay.
- Specimens with S/CO values ≥ 1.00 are considered reactive by the ARCHITECT Syphilis TP assay.

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 ARCHITECT System 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 ARCHITECT 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

Precision

The ARCHITECT Syphilis TP assay precision is ≤ 15% for the positive control. Precision was determined as described in the Clinical and Laboratory Standards Institute (CLSI), Protocol EP5-A2.[6] Six samples consisting of four plasma based panels and both of Syphilis TP Controls were assayed in replicates of two at two separate times per day for twenty days (n=80 for each sample), using three lots of reagents. Data from this study are summarized in the following table.*

ARCHITECT Syphilis TP Precision

			Repeatability[a]		Within-laboratory[b]	
Sample	Lot	Mean S/CO	SD	%CV	SD	%CV
Negative Control	1	0.04	0.002	5.4	0.002	5.4
	2	0.04	0.005	14.3	0.005	14.7
	3	0.03	0.004	13.1	0.004	13.6
Positive Control	1	2.66	0.048	1.8	0.060	2.3
	2	2.65	0.066	2.5	0.094	3.6
	3	2.66	0.048	1.8	0.069	2.6
Panel D1	1	6.49	0.108	1.7	0.133	2.0
	2	6.57	0.099	1.5	0.144	2.2
	3	6.62	0.116	1.8	0.143	2.2
Panel D2	1	3.74	0.074	2.0	0.092	2.5
	2	3.73	0.059	1.6	0.091	2.4
	3	3.78	0.068	1.8	0.089	2.3
Panel D3	1	1.89	0.034	1.8	0.043	2.3
	2	1.88	0.035	1.9	0.048	2.6
	3	1.89	0.034	1.8	0.048	2.5
Panel D4	1	0.75	0.014	1.8	0.019	2.5
	2	0.74	0.017	2.3	0.020	2.8
	3	0.75	0.015	2.0	0.018	2.5

[a] Repeatability corresponds to within-run variance.

[b] Within-laboratory variance is an accumulation of within-run, between-run and between-day variance.

* Representative data; results in individual laboratories may vary from these data.

Specificity

A study to evaluate performance was conducted at one internal site. Of 5174 BD specimens, 3 specimens were confirmed falsely reactive by ARCHITECT Syphilis TP assay, after resolution. Of 1262 hospitalized/diagnostic specimens, three specimen were falsely reactive by ARCHITECT Syphilis TP assay. The data from this study are summarized in the following table.*

Specificity Results Using Random Blood Donors and Hospitalized Patients

Category	n	IR [%]	RR [%]	Specificity	95% Confidence Interval
Overall Blood Donors	5174	3 [0.06]	3 [0.06]	99.94% (5171/5174)	99.83 - 99.99%
Blood Donor Plasma	2587	3 [0.12]	3 [0.12]	99.88% (2584/2587)	99.66 - 99.98%
Blood Donor Serum	2587	0 [0.00]	0 [0.00]	100.00% (2587/2587)	99.86 - 100%
Hospitalized/ Diagnostic Specimens	1262	3 [0.24]	3 [0.24]	99.76% (1259/1262)	99.31 - 99.95%

* Representative data; results in individual laboratories may vary from these data.

Sensitivity

The ARCHITECT Syphilis TP assay demonstrated a sensitivity of ≥ 99.0% in a study testing samples that were confirmed as true positive. The data from this study are summarized in the following table.*

Sensitivity Result

n	Lot	Reactive	Nonreactive	Observed Sensitivity
409	1	409	0	100%
409	2	409	0	100%
409	3	409	0	100%
409	4	409	0	100%

* Representative data; results in individual laboratories may vary from these data.

Interference

Potential interference from elevated levels of triglycerides, bilirubin, protein and hemoglobin in the ARCHITECT Syphilis TP assay is < 0.40 S/CO difference on negative specimens and < 20% S/CO difference on positive samples with the following concentrations.

Test Compound	Test Concentration
Triglycerides	3000 mg/dL
Bilirubin	20 mg/dL
Protein	12 g/dL
Hemoglobin	500 mg/dL

BIBLIOGRAPHY

1. Meyer JC. Laboratory Diagnosis of Syphilis. *Curr Probl Dermatol.* 1996; 24: 1-11.
2. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
3. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
4. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
5. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
6. National Committee for Clinical Laboratory Standards (NCCLS). *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* NCCLS Document EP5-A2. Wayne, PA: NCCLS; 2004.
7. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. Guidance for Industry Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), November 2004. http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073972.htm Accessed October 24, 2017.

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.
CONTROL NO.	Control Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF GERMANY	Product of Germany
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
TRIGGER SOLUTION	Trigger Solution
WARNING: EYE IRRITANT	Warning: Causes serious eye irritation.
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer

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

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