



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.

## NAME

ARCHITECT Ferritin

## INTENDED USE

The ARCHITECT Ferritin assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of ferritin in human serum and plasma.

## SUMMARY AND EXPLANATION OF THE TEST

Ferritin is a high-molecular weight iron-containing protein that functions in the body as an iron storage compound. Each ferritin molecule is thought to consist of a spherical protein shell of molecular weight about 460,000 daltons made up of 24 subunits with a variable amount of iron as a core of ferric oxide-phosphate.<sup>1</sup> It has been demonstrated that the ferritin molecule, when fully saturated, may consist of over 20% iron by weight.<sup>2</sup>

Approximately 25% of the iron in a normal adult is present in various storage forms.<sup>3</sup> About two-thirds of the iron stores in the human body exist in the form of ferritin. The remaining iron stores are contained in insoluble hemosiderin, which most likely represents a form of denatured ferritin.<sup>4</sup>

The availability of sensitive methods for measuring serum ferritin have significantly advanced the ability to detect iron deficiency and overload. Since iron deficiency is present before the onset of anemia, detection of an iron depleted state is important for the control of nutritional anemia. The clinical assessment of iron stores has historically relied on the determination of serum iron, total iron-binding capacity (TIBC) and percent transferrin (ratio of serum iron and TIBC) or direct examination of bone marrow.

The estimation of storable iron in the bone marrow is the traditional method for assessing body iron stores. This biopsy method provides a sensitive index of iron deficiency but has the disadvantage of being subjective and semiquantitative. Low hemoglobin concentration is the most readily available sign of anemia, but a significant fall in circulating hemoglobin cannot be detected until the final stage of iron deficiency anemia. Serum iron, TIBC and percent transferrin saturation do not distinguish iron deficiency as a progressive disease. Also, these measurements are affected by diurnal variation and may not discriminate between depleted iron stores and conditions associated with defective reticuloendothelial release of iron (e.g., anemia of chronic disease).<sup>3</sup> Recent literature suggests that ferritin provides a more sensitive, specific and reliable measurement for determining iron deficiency at an early stage.<sup>9</sup> In patients being given iron orally, serum ferritin measurements have been shown to be useful for monitoring the reaccumulation of iron stores and determining when therapy can be discontinued.<sup>10</sup> In chronic inflammatory disorders, infections, and in chronic renal failure, there is a disproportionate increase in serum ferritin levels in relation to iron stores. The correlation of serum ferritin to body iron stores still exists, however, it is set at a higher level of serum ferritin.<sup>7, 8</sup> Numerous studies in the literature demonstrate the usefulness and necessity of serum ferritin measurements in combination with other parameters in determining the rate and degree of body iron overload in such disorders as thalassemia, sideroblastic anemia and in determining the response of patients treated with iron chelating

agents.<sup>5, 6</sup> Specifically, the combined use of serum ferritin levels and mean corpuscular volume (MCV) has made differentiation between iron deficiency, beta-thalassemia trait and normal subjects possible at a very high level of accuracy.<sup>11, 12</sup>

## BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

1. Sample, and anti-ferritin coated paramagnetic microparticles are combined. The ferritin present in the sample binds to the anti-ferritin coated microparticles.
2. After washing, anti-ferritin 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 ferritin 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 Ferritin 7K59

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

REF	7K59-25	7K59-20	7K59-35	7K59-30
$\Sigma$	100	400	500	2000
<b>MICROPARTICLES</b>	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
<b>CONJUGATE</b>	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL	4 x 26.3 mL

**MICROPARTICLES** Anti-Ferritin (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (mouse and bovine) stabilizers. Minimum Concentration: 0.125% solids. Preservative: antimicrobial agent.

**CONJUGATE** Anti-Ferritin (rabbit, polyclonal) acridinium labeled Conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 75 ng/mL. Preservative: antimicrobial agent.

### 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.<sup>13-16</sup>

Safety Data Sheets are available at [www.abbottdiagnostics.com](http://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
<b>Unopened/Opened*</b>	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage. Store in upright position.
<b>On board</b>	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 Ferritin assay file must be installed on the ARCHITECT iSystem 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	Tripotassium EDTA Lithium heparin

- Individual plasma concentration values may differ from serum by more than 10%.
- Samples in tripotassium EDTA may give values below those of serum, while samples collected in lithium heparin may give values greater than serum values.
- Other anticoagulants have not been verified for use with the ARCHITECT Ferritin assay.
- Other specimen collection tube types have not been tested with this assay.
- When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
- 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.

### Specimen Conditions

- For optimal results, serum and plasma specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

### Preparation for Analysis

- Follow the tube manufacturer's processing instructions for specimen collection tubes.
- Specimens must be mixed **THOROUGHLY** after thawing, by **LOW** speed vortexing or by gently inverting, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results.
- 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
Human serum or plasma	2-8°C	≤ 7 days

If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells.

If testing will be delayed more than 7 days, specimens should be frozen at -10°C or colder.

Specimens stored frozen at -10°C or colder for 12 months showed no performance difference.

Multiple freeze-thaw cycles of specimens should be avoided.

## 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.

## PROCEDURE

### Materials Provided

7K59 ARCHITECT Ferritin Reagent Kit

### Materials Required but not Provided

- ARCHITECT Ferritin Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com).
- 7K59-01 ARCHITECT Ferritin Calibrators
- 7K59-10 ARCHITECT Ferritin Controls
- 7D82-50 ARCHITECT Multi-Assay Manual Diluent
- 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, place a septum on the bottle. For instructions about 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: 70 µL
      - Sample volume for each additional test from same sample cup: 20 µL
    - ≤ 3 hours on board:
      - Sample volume for first test: 150 µL
      - Sample volume for each additional test from same sample cup: 20 µL
    - > 3 hours on board: Additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.
    - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
  - Prepare ARCHITECT Ferritin Calibrators 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: 4 drops
      - for each control: 3 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 with a ferritin value exceeding 2000 ng/mL are flagged with the code “ >2000 ” and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

#### Automated Dilution Protocol

The system performs a 1:20 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.

#### Manual Dilution Procedure

Suggested dilution: 1:20

1. Add 20 µL of the patient specimen to 380 µL of ARCHITECT Multi-Assay Manual Diluent.
2. The operator must enter the dilution factor in the patient or control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result. The dilution should be performed so that the diluted result reads greater than 80 ng/mL. If the diluted result reads less than 80 ng/mL, the sample should be retested undiluted.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

## Calibration

- Test Calibrators 1 and 2 in duplicate. The calibrators should be priority loaded.  
A single replicate 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.
- Calibration Range: 0 - 1000 ng/mL.
- The assay protocol extends the assay range to 0 - 2000 ng/mL.
- Once an ARCHITECT Ferritin 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 Ferritin assay is that a single replicate 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 concentration ranges specified in the package insert for controls.

## Verification of Assay Claims

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

The ARCHITECT Ferritin assay belongs to method group 1.

For the analytical sensitivity calculation, follow method group 1 and divide the result by 2.

## RESULTS

The ARCHITECT Ferritin assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, X-weighted) to generate a calibration curve.

## 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

- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- If the Ferritin results are inconsistent with clinical evidence, additional testing is recommended.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as ARCHITECT Ferritin that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.<sup>17, 18</sup>
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.<sup>19</sup>

## EXPECTED VALUES

Evaluation of serum specimens from 32 normal males and 60 normal females with the ARCHITECT Ferritin assay yielded the following results.

Normal Range Summary	No. of Subjects	Median (ng/mL)	Central 95% Interval (ng/mL)
Males	32	75.62	21.81 - 274.66
Females	60	39.42	4.63 - 204.00

These individuals were determined to be normal based on the AxSYM Ferritin Assay. It is recommended that each laboratory establish its own range, which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.

Ferritin levels below 10 ng/mL have been reported as indicative of iron deficiency anemia.<sup>20, 21</sup> There are patients with iron deficiency anemia who have elevated or normal ferritin levels because of other causes, such as hepatocellular disease or iron therapy.<sup>4, 7</sup>

## SPECIFIC PERFORMANCE CHARACTERISTICS

### Precision

The ARCHITECT Ferritin assay is designed to have a precision of  $\leq 9$  total %CV for concentrations within the range of the low, medium and high control (Panel Members 1-3). A study based on guidance from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EP5-T2 was performed for the ARCHITECT Ferritin assay.<sup>22</sup>

A three member buffered protein based panel (1, 2, and 3) and a three member reconstituted processed human serum panel (4, 5, and 6) were assayed in replicates of two at two separate times per day, for 20 days on one instrument using two lots of reagents and a single calibration for each reagent lot. Data from this study are summarized in the following table.

Panel Member	Reagent Lot	Instrument	n	Mean	Within Run		Total	
				Conc. Value (ng/mL)	SD	%CV	SD	%CV
1	1	1	80	20.33	0.723	3.6	0.968	4.8
1	2	1	80	19.08	0.818	4.3	1.217	6.4
2	1	1	80	148.07	5.760	3.9	8.417	5.7
2	2	1	80	145.38	5.303	3.6	8.096	5.6
3	1	1	80	391.47	15.574	4.0	21.593	5.5
3	2	1	80	387.61	13.012	3.4	21.703	5.6
4	1	1	80	421.13	15.847	3.8	25.080	6.0
4	2	1	80	408.61	14.353	3.5	21.504	5.3
5	1	1	80	155.03	5.338	3.4	14.962	9.7
5	2	1	80	149.89	5.226	3.5	15.514	10.3
6	1	1	80	40.52	1.286	3.2	4.500	11.1
6	2	1	80	39.22	1.336	3.4	4.600	11.7

### Recovery

The ARCHITECT Ferritin assay is designed to have a mean recovery of  $100 \pm 10\%$  when analyzing samples spiked with known amounts of ferritin. Known concentrations of ferritin were added to five human serum specimens. In a study, the concentration of ferritin was determined using the ARCHITECT Ferritin assay and the resulting percent recovery was calculated.

Sample	Endogenous Ferritin Conc. (ng/mL)	Ferritin Added (ng/mL)	Observed Ferritin Conc. (ng/mL)	Percent Recovery
1	21.19	85.72	100.27	92.3
	21.19	262.26	267.77	94.0
	21.19	423.92	440.40	98.9
2	82.17	85.72	171.85	104.6
	82.17	262.26	328.15	93.8
	82.17	423.92	510.35	101.0
3	175.40	85.72	250.67	87.8
	175.40	262.26	404.20	87.2
	175.40	423.92	606.72	101.7
4	246.95	85.72	327.98	94.5
	246.95	262.26	485.28	90.9
	246.95	423.92	662.04	97.9
5	452.76	85.72	550.16	113.6
	452.76	262.26	738.96	109.1
	452.76	423.92	924.84	111.4

Average Recovery: 98.6%

$$\% \text{ Recovery} = \frac{\text{Observed Ferritin Conc. (ng/mL)} - \text{Endogenous Ferritin Conc. (ng/mL)}}{\text{Ferritin Added (ng/mL)}} \times 100$$

### Analytical Sensitivity

The ARCHITECT Ferritin assay is designed to have an analytical sensitivity of  $\leq 1$  ng/mL. Analytical sensitivity is defined as the concentration at two standard deviations from the mean RLU value of the ARCHITECT Ferritin MasterCheck Level 0 (0.0 ng/mL), and represents the lowest measurable concentration of ferritin that can be distinguished from zero. The mean analytical sensitivity of the ARCHITECT Ferritin assay was calculated to be  $< 1$  ng/mL (n=36 runs).

### Interference/Specificity

The ARCHITECT Ferritin assay is designed to have  $\leq 10\%$  mean interference from hemoglobin, bilirubin, triglycerides, and protein at the levels indicated below. Potential interference from these four components was studied in the ARCHITECT Ferritin assay. The ARCHITECT Ferritin assay demonstrated  $\leq 10\%$  mean interference at the levels indicated below.

- Hemoglobin 200 mg/dL
- Bilirubin 20 mg/dL
- Triglycerides 3000 mg/dL
- Protein 2 g/dL and 12 g/dL

### Accuracy by Correlation

The ARCHITECT Ferritin assay demonstrated a slope of  $1.2 \pm 0.2$  and a correlation coefficient (r) of  $\geq 0.95$  in the 1-1000 ng/mL range when compared to the AxSYM Ferritin assay. A study was performed where specimens were tested using ARCHITECT Ferritin assay and AxSYM Ferritin assay. Data from this study were analyzed using least squares and Passing Bablok regression methods and are summarized in the following table.\*\*\*

Abbott ARCHITECT Ferritin vs. Abbott AxSYM Ferritin

Method	Number of Specimens	Range* (ng/mL)	Intercept	Slope	Correlation Coefficient
Least Squares	436	1 - 1000 <sup>1</sup>	-4.86	1.18	0.979
Linear Regression	518	1 - 2000 <sup>2</sup>	-3.65	1.18	0.986
Passing-Bablok**	436	1 - 1000 <sup>1</sup>	-1.52	1.16	0.979
Linear Regression	518	1 - 2000 <sup>2</sup>	-1.89	1.17	0.986

In this evaluation, serum specimens tested on the ARCHITECT Ferritin assay ranged from <sup>1</sup>1.39 to 1510.64 and <sup>2</sup>1.39 to 1967.46 ng/mL. Serum specimens tested on the AxSYM Ferritin assay ranged from <sup>1</sup>1.37 to 997.17 and <sup>2</sup>1.37 to 1827.47 ng/mL.

\* Range established from AxSYM Ferritin values.






\*\* A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.<sup>23</sup>

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


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## ■ Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
<b>CONJUGATE</b>	Conjugate
<b>CONTROL NO.</b>	Control Number
<b>DISTRIBUTED IN THE USA BY</b>	Distributed in the USA by
<b>INFORMATION FOR USA ONLY</b>	Information needed for United States of America only
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>MICROPARTICLES</b>	Microparticles
<b>MULTI-ASSAY MANUAL DILUENT</b>	Multi-Assay Manual Diluent
<b>PRE-TRIGGER SOLUTION</b>	Pre-Trigger Solution
<b>PRODUCT OF IRELAND</b>	Product of Ireland
<b>REACTION VESSELS</b>	Reaction Vessels
<b>REAGENT LOT</b>	Reagent Lot
<b>REF</b>	List Number
<b>REPLACEMENT CAPS</b>	Replacement Caps
<b>SAMPLE CUPS</b>	Sample Cups
<b>SEPTUM</b>	Septum
<b>SN</b>	Serial number
<b>TRIGGER SOLUTION</b>	Trigger Solution
<b>WASH BUFFER</b>	Wash Buffer

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