VIDAS® T4 (T4)

Rx only IVD

The VIDAS® T4 (T4) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.

SUMMARY AND EXPLANATION OF THE TEST

Thyroxine (T4), or tetraiodothyronine, was isolated in 1919 by Kendall and its structure was established in 1926. T4 is a 777 dalton molecular weight iodine-containing hormone secreted by the thyroid gland (1,4).

T4 circulates in the bloodstream as a mixture of free and serum protein-bound hormone. The majority (> 99%) of T4 is bound to carrier proteins, mainly to thyroxine binding globulin (TBG) and to a lesser degree to thyroxine binding prealbumin (TBPA) and albumin. The free fraction (FT4) only represents < 0.1% of the total T4 concentration and is the biologically active fraction (1).

T4 measurements are recognized as a good indicator of thyroid function. In hyperthyroid subjects, T4 is characteristically elevated whereas in hypothyroid subjects the concentration is usually decreased.

T4 concentrations are altered by physiological or pathological changes in thyroxine binding globulin (TBG) capacity (2,5). For example, factors such as estrogen, glucocorticoid or androgen therapy, pregnancy, oral contraceptives, nephrotic syndrome, and genetic influences can cause substantial changes in TBG levels (2,5). In neonates or children, T4 levels are higher than in the normal adults due to the increased TBG concentration.

Consequently, while T4 concentrations give good indications of thyroid status in many cases, compensatory changes in T4 levels can also occur and T4 levels alone may give a false impression of thyroid function.

Therefore, the accurate diagnosis of thyroid status should include other thyroid hormone testing such as TSH, T3, or T-uptake in conjunction with clinical evaluations (3).

PRINCIPLES OF THE PROCEDURE

The VIDAS T4 (T4) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. At the time of manufacture, the SPR®s are coated with mouse monoclonal anti-T4 antibodies. The VIDAS T4 (T4) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are in the sealed T4 Reagent Strips.

The sample is transferred into the well containing the T4 antigen conjugated with alkaline phosphatase. The conjugate solution also contains ANS and sodium salicylate, which liberate bound T4 from the carrier proteins in the sample. The sample/conjugate mixture is cycled in and out of the SPR and the T4 in the sample competes with the T4-alkaline phosphatase conjugate for binding with the mouse monoclonal anti-T4 antibodies coated on the SPR.

Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled in and out of the SPR. Enzyme remaining on the SPR well will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone (450 nm). The intensity of fluorescence is measured by the optical scanner in the instrument. It is inversely proportional to the T4 concentration present in the sample.

When the VIDAS T4 (T4) is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

KIT COMPOSITION (60 TESTS):

60 T4 Reagent Strips	STR	Ready-to-use.
60 T4 SPRs (2 x 30)	SPR	Ready-to-use. SPRs are coated with mouse monoclonal anti-T4 antibodies.
T4 Control (liquid) (1 x 3 ml)	C1	Ready-to-use. Human sera* with L-thyroxine and sodium azide. MLE data indicate the confidence interval in nmol/l ("Control C1 Dose Value Range").
T4 Calibrator (liquid) (1 x 4 ml)	S1	Ready-to-use. Human serum* with L-thyroxine and sodium azide. MLE data indicate the dose value in nmol/ml ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range).
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit or • MLE barcodes printed on the box label.		
1 Package Insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

* This product has been tested and shown to be negative for HBs antigen, antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, the usual safety procedures should be observed when handling

The SPR®

The interior of the SPR is coated during production with anti-T4 monoclonal antibodies (mouse). Each SPR is identified by the "T4" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening.**

The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the T4 Reagent Strip

Wells	Reagents
1	Sample well
2-3-4-5	Empty wells
6	Conjugate: A derivative of T4 antigen conjugated to alkaline phosphatase with ANS (0.8 mmol/l), sodium salicylate (9.3 mmol/l), and 1 g/L sodium azide (400 µl)
7	Wash buffer: TRIS buffered saline (0.05 mol/l, pH 7.4) with 1 g/L sodium azide (600 µl)
8	Wash buffer: TRIS buffered saline (0.05 mol/l, pH 7.4) with Tween 20 (0.05%) and 1g/L sodium azide (600 µl)
9	Wash buffer: diethanolamine* (DEA)(1.1 mol/l or 11.5%, pH 9.8) + 1 g/l sodium azide (600 µl).
10	Reading cuvette with substrate: 4-methyl-umbelliferyl phosphate (0.6 mmol/l) + diethanolamine** (0.62 mol/l or 6.6%, pH 9.2) + 1 g/l sodium azide (300 µl).

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

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For further information, refer to the Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipette with disposable tips that will dispense 200 µl.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family: VIDAS, miniVIDAS or VIDAS 3.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).

- Consider all patient specimens potentially infectious and observe routine biosafety precautions.
- Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products.
- Do not mix reagents or disposables from different lots.
  Kit reagents contain 1 g/L sodium azide which could react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- Powderless gloves are recommended as powder has been reported as a cause of false results in some enzyme immunoassays.
- The wash buffer (well 9) contains a harmful agent (11.5 % diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5 % sodium hypochlorite to inactivate infectious agents. See the Operator's Manual for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS® T4 (T4) Kit at 2-8ºC. **Do not freeze reagents.** Return unused components to 2-8ºC.
  - After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
  - **Carefully reseal the pouch with the desiccant inside after use to maintain the stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.

SPECIMEN COLLECTION AND PREPARATION

Acceptable specimens include serum or plasma (with heparin anticoagulant). Do not use plasma collected with EDTA. The use of heat inactivated sera has not been established with this test - do not heat sera. Samples can be stored at 2-8ºC in stoppered tubes for up to 2 days. If longer storage is required, the serum or plasma can be stored at -25 ± 6°C for up to 2 months. Avoid repeated cycles of freezing and thawing. If necessary, clarify samples by centrifugation.

INSTRUCTIONS FOR USE

For complete instructions, see the Operator's Manual.

Reading Master lot data

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.

If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.

Note: the master lot data need only be entered once for each lot.
It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the Operator's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrator, identified by S1, must be tested in **triplicate** (see the Operator's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

ASSAY PROCEDURE

1. Remove necessary components from the kit and return all unused components to storage at 2-8ºC.
2. Allow components to reach room temperature (approximately 30 minutes).
3. Use one "T4" strip and one "T4" SPR for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
4. The test is identified by the "T4" code on the instrument. The calibrator must be identified by "S1", and tested in **triplicate**. If the control is to be tested, it should be identified by "C1".
5. If needed, label the "T4" Reagent Strips with the appropriate sample identification numbers.
6. Mix the calibrator, control, and sample using a vortex-type mixer (for serum or plasma separated from the pellet).
7. **For this test, the calibrator, control, and sample test portion is 200 µl.**
8. Insert the "T4" Reagent Strips and SPR®s into appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
9. Initiate the assay processing as directed in the Operator's Manual. All steps will be executed automatically by the instrument.
10. Reclose the vials and return them to 2–8°C after pipetting.
11. The assay will be completed within approximately 40 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
12. Dispose of the used SPRs and strips into an appropriate recipient.

QUALITY CONTROL

A control is included in each VIDAS® T4 (T4) kit. This control must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using this control. The instrument will only be able to check the control value if it is identified by C1.
Results cannot be validated if the control value deviates from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

RESULTS AND INTERPRETATION

Two instrument readings for fluorescence in the Reagent Strip's reading cuvette are taken for each specimen tested. The first reading is a background reading of the cuvette and substrate before the SPR is introduced into the substrate.
The second reading is taken after the substrate has been exposed to the enzyme conjugate remaining on the interior of the SPR. The background reading is subtracted from the final reading to give a Relative Fluorescence Value (RFV) for the test result.
Samples with results greater than 320 nmol/l are reported as ">320 nmol/l". These samples may be diluted 1/2 (1 volume of sample and 1 volume of T4 free serum) and retested in the VIDAS® T4 (T4) assay.
If the dilution factor has not been entered when the analysis has been requested (see Operator's Manual), multiply the result by the dilution factor to obtain the thyroxine sample concentration.

A report is printed which records :

- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and the expiration date of the reagent kit being used,
- each sample's RFV and T4 concentration.

LIMITATIONS OF THE TEST

1. The results of a T4 assay, included as part of a thyroid profile, should not be interpreted without the results of a TSH.
2. The T4 assay should be used in conjunction with other information gathered by the physician (e.g. symptoms, clinical observations, and other examinations etc.).
3. The use of neonatal specimens has not been established for the VIDAS T4 (T4) assay.

PERFORMANCE DATA

Immunological Specificity

The antibody used in the VIDAS T4 (T4) assay was tested for cross-reactivity against a number of compounds. The results in the table below are represented as the percentage ratio between the T4 concentration and the cross reactant concentration at 50 % binding.

Tested compound	Cross-reactivity percentage
L-thyroxine	100 %
D-thyroxine	83 %
L-Triiodothyronine	2.3 %
D-Triiodothyronine	1.8 %
Diiodotyrosine	< 0.01 %
Diiodothyronine	< 0.01 %
Diphenylhydantoïn	< 0.01 %
Propylthiouracil	< 0.01 %
Sodium Salicylate	< 0.01 %

Detection limit – VIDAS/miniVIDAS

The detection limit (assay sensitivity) is defined as the lowest concentration that can be distinguished from zero with 95 % probability. The detection limit for the VIDAS T4 (T4) assay is 6 nmol/l.

Detection limit – VIDAS 3

The detection limits (Limit of Blank LoB, Limit of Detection LoD, Limit of Quantification LoQ) of the VIDAS T4 assay on the VIDAS 3 were evaluated per CLSI EP17-A2 and were: LoB = 1.596 nmol/L; LoD = 3.749 nmol/L; LoQ = 6.216 nmol/L.

Linearity – VIDAS 3

Linearity was evaluated per CLSI EP06-A and it was determined that the VIDAS T4 assay on VIDAS 3 is linear across the measuring range 6 – 320 nmol/L.

PRECISION/REPRODUCIBILITY – VIDAS/MINIVIDAS

Intra-assay precision

Five samples were tested for intra-assay precision. Thirty replicates of each sample were tested in the same run.

Sample	1	2	3	4	5
Mean concentration (nmol/l)	33.0	61.1	93.9	166.6	238.5
% CV	9.0	5.1	4.7	5.0	5.9

Inter-assay reproducibility on the same instrument

Five samples were tested in singlet on the same instrument over an 8 week-period (recalibration was performed every 14 days as described in the Operator's Manual).

Sample	1	2	3	4	5
Mean concentration (nmol/l)	27.5	55.3	85.4	150.8	233.1
% CV	8.6	6.2	6.0	5.0	7.6

Inter-instrument and inter-assay reproducibility

Five samples were tested in singlet in 8 runs on different instruments.

Sample	1	2	3	4	5
Mean concentration (nmol/l)	30.3	56.9	89.5	158.9	237.9
% CV	9.1	2.6	4.3	2.5	6.1

PRECISION/REPRODUCIBILITY – VIDAS 3

Five serum samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The results were calculated according to CLSI EP5-A2 and were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (nmol/L) 12.8		Mean (nmol/L) 35.14		Mean (nmol/L) 63.60		Mean (nmol/L) 121.99		Mean (nmol/L) 227.17	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	1.17	9.1	1.54	4.4	1.88	3.0	4.24	3.5	12.46	5.5
Between-RUN	0.00	0.0	0.00	0.0	0.62	1.0	1.53	1.3	0.00	0.0
Between-DAY	0.76	6.0	0.00	0.0	0.34	0.5	0.00	0.0	4.74	2.1
Total Between-INSTRUMENT	1.48	11.6	1.80	5.1	2.47	3.9	4.66	3.8	13.96	6.1

PARALLELISM (DILUTION TESTS)

Three samples were diluted in human T4-free serum and each dilution was tested in 3 runs. The measured mean values compared to the expected mean values are shown below as the mean recovery percentages.

Sample	Dilution factor	Expected mean values (nmol/l)	Measured mean values (nmol/l)	Mean recovery percentage
1	1:1	127.7	127.7	100.0
	1:2	63.8	68.0	106.5
	1:4	31.9	36.6	114.7
2	1:1	251.2	251.2	100.0
	1:2	125.6	121.4	96.6
	1:4	62.8	66.2	105.4
3	1:1	183.2	183.2	100.0
	1:2	91.6	90.1	98.4
	1:4	45.8	53.4	116.6

RECOVERY TESTS

Three samples were spiked with known quantities of T4 and tested in 3 runs. The measured mean concentrations compared to the expected mean concentrations are shown below as the mean recovery percentages:

Sample	Amount spiked (nmol/l)	Expected mean concentration (nmol/l)	Measured mean concentration (nmol/l)	Mean recovery percentage
1	0	35.8	35.8	100.0
	11.8	47.6	48.2	101.2
	21.4	57.2	59.3	103.6
	40.2	76.0	78.8	103.6
	80.8	116.6	108.4	92.9
	164.0	199.8	185.9	93.0
2	0	38.2	38.2	100.0
	11.8	50.0	51.7	103.4
	21.4	59.6	59.5	99.8
	40.2	78.4	83.5	106.5
	80.8	119.0	113.0	95.2
	164.0	202.2	192.8	95.4
3	0	40.5	40.5	100.0
	11.8	52.3	57.5	109.9
	21.4	61.9	60.0	96.9
	40.2	80.7	78.0	96.7
	80.8	121.3	114.5	94.3
	164.0	204.5	189.3	92.6

INFLUENCE OF SPECIMEN COLLECTION

Blood samples were collected from twenty-five patients. For each patient, three specimens were collected at the same time: in a dry glass tube, in a tube with separating gel, and in a heparinized tube. Each sample collected was tested in duplicate and sera from the same donor were tested in the same run. The dry glass tube was the reference to which the other methods were compared. The statistical ratio method that was used to evaluate the data showed that there was no significant difference with any of the specimen collection devices tested.

INTERFERENCE STUDIES

Heparin

Three pools of human sera were spiked with increasing quantities of heparin.

		Amount of heparin spiked (IU/ml)			
		0	0.5	5	50
T4 (nmol/l)	Pool 1	26.5	24.6	24.4	22.4
	Pool 2	53.3	53.1	52.4	51.5
	Pool 3	218.9	230.4	225.4	214.7

EDTA

Three pools of human sera were spiked with increasing quantities of EDTA.

		Amount of EDTA spiked (mg/ml)			
		0	1	5	10
T4 (nmol/l)	Pool 1	26.5	29.6	36.2	36.0
	Pool 2	53.3	54.5	58.0	72.3
	Pool 3	218.9	229.6	278.6	> 320.0

The presence of EDTA in the samples leads to a rise in values. Only plasma collected with heparin can be used.

Hemoglobin

Two pools of human sera were spiked with increasing quantities of hemoglobin obtained from a lysate of human red blood cells.

		Amount of hemoglobin spiked (µmol/l)						
		0	15	30	60	150	210	300
T4 (nmol/l)	Pool 1	77.9	77.3	72.2	74.0	79.0	76.8	82.2
	Pool 2	74.6	73.8	72.5	78.0	74.3	76.6	79.8

Lipids

Two pools of human sera were spiked with increasing quantities of a lipid solution.

		Amount of triglycerides spiked (mmol/l)				
		0	1.0	2.6	3.0	5.0
T4 (nmol/l)	Pool 1	78.1	73.6	76.8	75.9	75.7
	Pool 2	67.6	76.4	69.1	72.5	67.5
Appearance		Clear	Opalescent		Turbid	

Bilirubin

Two pools of human sera were spiked with increasing quantities of bilirubin.

		Amount of bilirubin spiked (µmol/l)						
		0	19.6	38.5	78.8	182.0	244.1	265.0
T4 (nmol/l)	Pool 1	77.1	76.7	78.0	74.4	74.7	74.7	82.7
	Pool 2	73.5	74.4	77.5	83.8	74.1	74.9	76.9

Although interference linked to the presence of hemoglobin, lipids, or bilirubin has not been observed, using hemolyzed, icteric or lipemic samples is not recommended. If possible, collect a new specimen.

EXPECTED VALUES

One hundred thirty three clinically or biologically euthyroid subjects without severe associated pathology were tested using the VIDAS® T4 (T4) assay. The following range is within a 95% confidence limit of the results observed in this study. Expected range: 60-120 nmol/l.

It is advisable for each laboratory to establish its own reference values from a well-defined population.

Conversion factors :

– From nmol/l to µg/dl multiply by 0.0777

– From nmol/l to µg/l multiply by 0.777.

CORRELATION – VIDAS/MINIVIDAS

Two hundred forty samples with T4 concentrations ranging from 35 to 288 nmol/l were tested using the VIDAS T4 (T4) assay and a commercially available T4 EIA. The results of the correlation are shown below :

# of samples	Equation of the line	Correlation Coefficient
240	y = 0.90x + 9.0	0.92

CORRELATION – VIDAS 3

A study was conducted to verify the correlation of the VIDAS T4 assay on the VIDAS 3 to the VIDAS T4 assay on the VIDAS. One reagent lot, one of each instrument and 105 serum samples were used. Results were evaluated according to CLSI EP9 and were as follows:

N	Slope	Intercept	Correlation Coefficient
105	0.9547	-0.6860	0.9866

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. BECKERS C. Thyroid hormone synthesis and circulating thyroid hormones. In Thyroid diseases, World federation of nuclear medicine and biology. Ed. C.Beckers, Pergamon Press, 1982, 1-21.
2. BIERSACK H.J. and HOTZE A. The clinician and the thyroid.. Eur. J. Nucl. Med., 1991, 18, 761-778.
3. HELFAND M. and CRAPO L.M. Screening for thyroid disease. Annals of Internal Medicine, 1990, 112 (11), 840-849.
4. PITT-RIVERS R. The thyroid hormones : Historical Aspects. Hormonal Proteins and Peptides, VI, techniques in protein chemistry. ; edited by C. H. LI New York Academic Press, 1978, 391-422.
5. SEGRESTAA J.M and BERGMAN J.F. Interférences des médicaments et des immunodosages hormonaux . Immunoanal. Biol. Spéc., 1989, 17, 27-33.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
Rx only	Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2015/07	13683D	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) MATERIALS REQUIRED BUT NOT PROVIDED WARNINGS AND PRECAUTIONS INSTRUCTIONS FOR USE PERFORMANCE DATA

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