VIDAS® LH (LH)

IVD

The VIDAS® LH (LH) assay is intended for use on the instruments of the VIDAS family (VITEK® ImmunoDiagnostic Assay System) as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human luteinizing hormone (LH) concentration in human serum or plasma (heparin).

SUMMARY AND EXPLANATION OF THE TEST

LH (luteinizing hormone, or luteotropin) is a glycoprotein with a molecular weight of approximately 30,000 daltons. Two polypeptide subunits, alpha and beta, form LH. The LH alpha subunit, composed of 89 amino acids, contains an amino acid sequence identical to that of FSH and very similar to that of TSH and hCG (7). The beta subunit, composed of 115 amino acids, contains an unique amino acid sequence which gives biological and immunological specificity to LH.

LH is secreted by gonadotropic cells of the anterior pituitary, controlled by the hypothalamus. In males, LH stimulates the production of testosterone by the Leydig cells. Testicular steroid hormones control the circulating level of LH via a negative-feedback mechanism (1).

In women, LH values are subject to cyclic variations (3,6). LH and FSH function in ovulation and development of the corpus luteum, which in turn produces progesterone. Progesterone (with estrogens) then exerts a negative-feedback on LH and FSH levels through hypothalamic gonadotropin releasing hormone (2,7). The measurement of LH is useful in the diagnosis and management of menstrual cycle disorders (3).

For both sexes, the measurement of LH is used to differentiate primary from secondary hypogonadism. Elevated LH levels indicate primary gonadal failure (hypergonadotropic hypogonadism) while low LH levels indicate secondary hypogonadism (hypogonadotropic hypogonadism) (7).

PRINCIPLE OF THE PROCEDURE

The VIDAS® LH (LH) assay is an enzyme-linked fluorescent immunoassay (ELFA) 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. The SPR is coated at the time of manufacture with mouse anti-LH monoclonal antibodies. The VIDAS LH (LH) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is cycled in and out of the SPR for a specified length of time. The sample is transferred into the well containing anti-LH antibody conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the LH will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich".

Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the LH concentration present in the sample.

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

KIT COMPOSITION (60 tests):

60 LH Reagent Strips	STR	Ready to use.
60 LH SPRs (2 x 30)	SPR®	Ready to use. SPRs coated with mouse monoclonal anti-LH antibodies.
LH Control (lyophilized) (1 x 3 ml)	C1	Reconstitute with 3 ml distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Human sera* with human LH. MLE data indicate the confidence interval in mIU/mL (milli-international units per milliliter) ("Control C1 Dose Value Range").
LH Calibrator (lyophilized) (3 x 2 ml)	S1	Reconstitute with 2 ml distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Contains phosphate buffer (0.05 mol/l, pH 7.4) with human LH and protein stabilizers. MLE data indicate the concentration in mIU/mL (2nd IS 80/552) ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value" ("Calibrator (S1) RFV Range").
LH Dilution buffer (liquid) (1 x 3 ml)	R1	Ready to use. Phosphate buffer (0.05 mol/l, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar code 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 and 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 mouse monoclonal anti-LH immunoglobulins. Each SPR is identified by the "LH" 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 LH Reagent Strip

Wells	Reagents
1	Sample well.
2-3-4-5	Empty wells
6	Conjugate: Mouse monoclonal anti-LH antibodies conjugated to alkaline phosphatase (calf intestine) with 1 g/L sodium azide (400 µl).
7-8	Wash buffer: Sodium phosphate (0.05 mol/l, pH 7.4) with chemical stabilizers and 1 g/L sodium azide (600 µl)
9	Wash buffer: diethanolamine* (1.1 mol/l or 11.5 %, pH 9.8) with 1 g/L sodium azide (600 µl)
10	Reading cuvette with Substrate: 4-methylumbelliferyl phosphate (0.6 mmol/l) with diethanolamine (DEA**) (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.

MATERIAL REQUIRED BUT NOT PROVIDED

- Pipette with disposable tips that will dispense 3 ml, 2ml and 200 µl.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.

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 up 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® LH (LH) Kit at 2-8°C.
- **Do not freeze reagents, with the exception of calibrators and controls after reconstitution**.
- **Store all unused reagents at 2-8°C.**
- 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 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. Refer to the kit composition table for special storage conditions.

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 for this test - do not heat sera. Samples can be stored at 2-8°C in stoppered tubes for up to 2 days. If longer storage is required, freeze the sera or plasma at -25 ± 6°C for up to 30 days. Avoid repeated cycles of freezing and thawing. If necessary clarify samples by centrifugation.

INSTRUCTIONS FOR USE

For complete instructions, see the User'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 User'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 duplicate** (see 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 2-8°C.
2. Allow the components to reach room temperature (approximately 30 minutes).
3. Use one "LH" strip and one "LH" SPR for each sample, control or calibrator to be tested. **Make sure that the storage pouch has been carefully resealed after the required SPRs have been removed.**
4. The test is identified by the "LH" code on the instrument. The calibrator must be identified by "S1", and tested **in duplicate**. If the control needs to be tested, it should be identified by "C1".
5. If needed, label the "LH" 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 "LH" Reagent Strips and SPR®s into the 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 the assay steps are performed automatically by the Instrument.
10. Reclose the vials and return them to the required temperature after pipetting.
11. The assay will be completed in 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® LH (LH) kit. This control must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each recalibration must also be checked using these controls. Each laboratory must follow their regulatory guidelines for quality control.

Note

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

RESULTS AND INTERPRETATION

Two instrument's 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 Fluorescent Value (RFV) for the test result.
Samples with concentrations greater than 100 mIU/ml must be diluted by 1/2 (1 volume of sample and 1 volume of LH dilution buffer) or 1/4 (1 volume of sample and 3 volume of LH dilution buffer). 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 LH 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 LH concentration.

PERFORMANCE DATA

Immunological Specificity

The cross-reactivity percentage is the ratio between the compound concentration to be tested and the LH concentration to be tested for a signal of 500 RFV.

Tested components	Cross-reactivity percentage
LH (SCRIPPS ref. L0815-lot n°399711)	100.0
FSH (SCRIPPS ref. F0612-lot n°727991)	0.1
TSH (SCRIPPS ref. T0115-lot n°148911)	0.1
hCG free alpha subunit (SCRIPPS ref. C0814-lot n°255091)	0.01
hCG (SCRIPPS ref. C0714-lot n°210164)	0.01

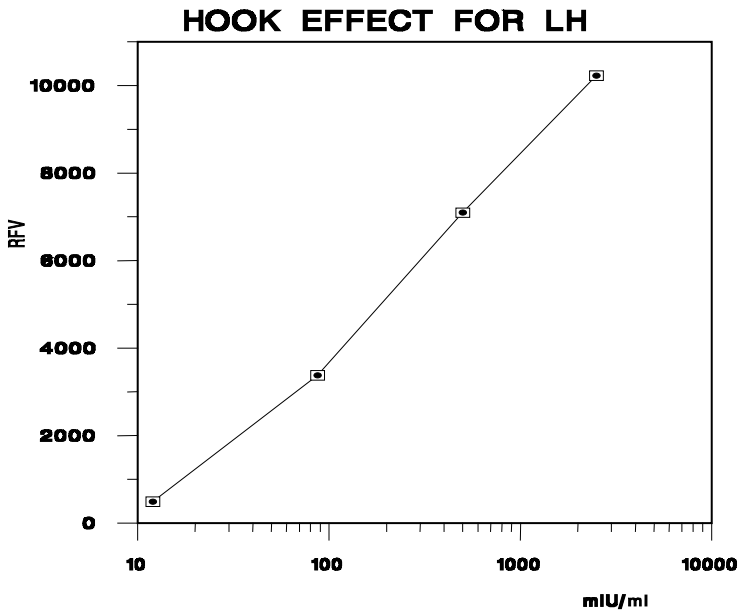
Immunological interference was tested by adding 315,000 mIU/ml of hCG or 10,000 mIU/ml of FSH to a sample containing 25 mIU/ml of LH. The interference percentage is a ratio of substance concentration to LH concentration.
No cross reactivity or interference in the VIDAS LH (LH) assay was observed with the substances tested.

Detection limit

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 LH (LH) assay is 0.1mIU/ml.

Hook Effect

The Hook effect was tested on two different kit lots using LH solutions; concentrations were from 12 to 2500 mIU/ml. No hook effect was seen at the concentrations tested.



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Calibration Range

PRECISION/REPRODUCIBILITY

Intra-assay reproducibility

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 (mIU/ml)	1.60	7.10	25.90	37.80	66.00
% CV	3.90	4.60	3.50	3.90	2.70

Inter-assay reproducibility on the same instrument

Five samples were tested in singlet in a total of 24 runs on the same instrument over a 9 week-period (recalibration was performed every 14 days as described in the Operator's Manual).

Sample	1	2	3	4	5
Mean concentration (mIU/ml)	1.67	7.20	26.30	33.30	65.00
% CV	3.80	6.60	4.00	4.50	3.70

Inter instrument and inter-assay reproducibility

Five samples were tested in singlet in 7 runs on different instruments.

Sample	1	2	3	4	5
Mean concentration (mIU/ml)	1.68	7.30	26.60	34.80	68.00
% CV	5.00	4.90	2.70	5.90	6.80

PARALLELISM (DILUTION TESTS)

Three samples were diluted in LH dilution buffer and tested in singlet in 3 runs.

Sample	Dilution factor	Expected values (mIU/ml)	Measured values (mIU/ml)	Recovery percentage
1	1/1	30.3	30.3	100.0
	1/2	15.2	15.2	100.0
	1/4	7.6	7.3	96.0
	1/8	3.8	3.5	93.0
	1/16	1.9	1.8	93.0
	1/32	0.9	0.8	89.0
2	1/1	40.0	40.0	100.0
	1/2	20.0	20.9	105.0
	1/4	10.0	9.8	98.0
	1/8	5.0	5.1	103.0
	1/16	2.5	2.5	101.0
	1/32	1.2	1.3	104.0
3	1/1	44.0	44.0	100.0
	1/2	22.0	24.5	111.0
	1/4	11.0	11.6	105.0
	1/8	5.5	5.8	106.0
	1/16	2.7	3.0	111.0
	1/32	1.4	1.4	100.0

Recovery Tests

Three samples were spiked with known quantities of LH (mIU, 2nd IS 80/552) and tested in singlet in 3 runs. The measured mean concentration compared to the expected mean concentration is shown below.

Sample	Amount Spiked (mIU/ml)	Expected mean concentration (mIU/ml)	Measured mean concentration (mIU/ml)	Mean recovery percentage
1	0	14.1	14.1	100.0
	2.5	16.6	15.9	96.0
	5.0	19.1	17.2	90.0
	12.5	26.6	24.7	93.0
	25.0	39.1	36.9	94.0
	50.0	64.1	61.5	96.0
2	0	21.3	21.3	100.0
	2.5	23.8	24.4	102.0
	5.0	26.3	25.5	97.0
	12.5	33.8	33.4	99.0
	25.0	46.3	42.4	91.0
	50.0	71.3	67.0	94.0
3	0	34.2	34.2	100.0
	2.5	36.7	37.8	103.0
	5.0	39.2	36.3	93.0
	12.5	46.7	44.2	95.0
	25.0	59.2	56.1	95.0
	50.0	84.2	78.3	93.0

INFLUENCE OF SPECIMEN COLLECTION

Blood samples were collected from thirty patients. For each patient, 5 specimens were collected at the same time: in a dry glass tube; in a tube with beads; in a tube with separating gel; in a heparinized tube; and in a EDTA tube. Each sample collected was tested in duplicate and sera from the same donor were tested in the same run. The tube with beads was the reference to which the other methods were compared.

Collection tube	Equation of the line	Correlation coefficient
Dry glass tube	y = 0.99 ref. - 0.04	0.99
Tube with separating gel	y = 1.01 ref. - 0.14	0.99
Tube with heparin (lithium)	y = 0.94 ref. + 0.04	0.99
Tube with EDTA	y = 0.80 ref. - 0.24	0.99

A decrease in values with EDTA tubes was observed. These tubes must not be used with the VIDAS LH (LH) assay.

INTERFERENCE STUDIES

Heparin

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

		Amount of heparin spiked (U/ml)			
		0	0.5	5	50
LH (mIU/ml)	Pool 1	1.6	1.6	1.5	1.6
	Pool 2	28.3	26.9	26.6	27.1
	Pool 3	42.1	42.5	43.0	41.0

EDTA

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

		Amount of EDTA spiked (mg/ml)			
		0	1	5	10
LH (mIU/ml)	Pool 1	1.6	1.5	0.8	0.3
	Pool 2	28.3	25.7	14.8	6.4
	Pool 3	42.1	39.0	24.5	11.4

The presence of EDTA in the samples diminishes the values obtained. Use only plasma collected with heparin.

Hemoglobin

Three 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
LH (mIU/ml)	Pool 1	1.58	1.51	1.64	1.59	1.66	1.66	1.61
	Pool 2	25.9	26.3	26.8	27.5	26.9	27.2	27.3
	Pool 3	40.6	40.8	41.2	40.9	41.3	41.4	42.3

Lipids

Three 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
LH (mIU/ml)	Pool 1	1.47	1.48	1.53	1.54	1.65
	Pool 2	27.2	25.7	25.2	26.7	25.8
	Pool 3	39.3	39.6	37.7	38.0	39.5
Appearance		Clear	Opalescent		Turbid	

Bilirubin

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

		Amount of bilirubin spiked (µmol/l)						
		0	25.6	51.3	102.6	256	385	513
LH (mIU/ml)	Pool 1	1.41	1.42	1.79	1.77	1.64	1.66	1.52
	Pool 2	25.7	27.0	27.3	27.1	27.0	25.9	25.6
	Pool 3	38.6	39.9	40.7	40.8	39.6	40.6	41.4

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

EXPECTED VALUES

Results are given in mIU/ml (2nd IS 80/552).
A study was performed at bioMérieux (Marcy l'Etoile, France) using samples from a healthy population and not infected with tumorous pathologies. For this study, the follicular phase has been defined as being the period between the 15th and 2nd day preceding ovulation. Luteal phase has been defined as being the period after the 3rd to the 15th day following ovulation. The days of the cycle have been defined as starting at the day where the concentration of LH is the most elevated. The following values were found :

Sample	n =	Results
- Men:	51	1.1 to 7.0 mIU/ml
- Women :		
Ovulation (Day 0)	20	9.6 to 80 mIU/ml
Follicular phase:		
1st half (D -15 to -9)	84	1.5 to 8.0 mIU/ml
2nd half (D -8 to -2)	118	2.0 to 8.0 mIU/ml
Luteal phase (D +3 to +15)	189	0.2 to 6.5 mIU/m
Menopausal women	51	8.0 to 33 mIU/ml

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

CORRELATION

Two hundred seventy-eight specimens were tested in a clinical chemistry laboratory. Specimens were tested using the LH assay and a commercially available immunoradiometric assay (IRMA). The results of linear regression analysis of the correlation are summarized below :

# of samples	Slope	Intercept	Correlation coefficient
278	0.962	0.018	0.99

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

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
	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
2015/01	13703C	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
2015/06	13703D	Technical	KIT COMPOSITION (60 tests) INSTRUCTIONS FOR USE

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