BECKMAN COULTER

CE 2797

AMH Gen II ELISA

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: PI-A79765-05	**Current version:** IFU-A79765-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added
—	CLSI guidelines incorporated

REF A79765

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

AMH Gen II ELISA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of Anti-Müllerian hormone (AMH) in human serum and plasma. Measurement of AMH is intended to be used for the assessment of fertility status and sexual development. In females, it is used to assess ovarian and menopausal status, including ovarian reserve, and as an aid in diagnosis of PCOS. It is used as an aid in differential diagnosis of intersex conditions in infants [1, 2, 3, 4].

PRINCIPLE

The enzyme immunoassay of AMH is an enzymatically amplified two-site assay. Mouse monoclonal antibodies directed against two different epitopes of AMH and hence not competing are used. Samples and calibrators are first incubated in wells coated with the monoclonal antibody. After the first incubation, the contents of the wells are rinsed and the wells are incubated with detection antibody labeled with biotin. After the second incubation, the contents of the wells are rinsed and the wells are incubated with streptavidin labeled with the enzyme horseradish peroxidase (HRP). After the third incubation the contents of the wells are rinsed and the wells are incubated with the substrate tetramethylbenzidine (TMB). The bound enzymatic activity is then measured after the addition of a chromogenic substrate. The AMH concentrations in the samples are obtained by interpolation from the standard curve. The concentration of AMH in the samples is directly proportional to the absorbance.

WARNING AND PRECAUTIONS

General remarks:

- Avoid exposure of the reagents to excessive heat or direct sunlight during storage and incubation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.
- Each well must be used only once.
- Incomplete washing will adversely affect the outcome and assay precision.
- Avoid microbial contamination of reagents, especially of the conjugate and the assay buffer.
- Avoid contamination of the TMB chromogen solution with the conjugates.
- For dispensing sulfuric acid and TMB chromogen solution, avoid pipettes with metal parts.
- The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

Materials of human origin

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

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GHS HAZARD CLASSIFICATION

Assay buffer	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Biotin conjugate	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Streptavidin conjugate	DANGER	
		
	H226	Flammable liquid and vapour.
	H302	Harmful if swallowed.
	H313	May be harmful in contact with skin
	H370	Causes damage to organs.
	P210	Keep away from heat, hot surfaces, and sparks. No smoking.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P308+P311	If exposed or concerned: Call a doctor/physician.
	P312	Call a POISON CENTER or doctor/physician if you feel unwell.
		Methanol 1 - 9%
Sample diluent	WARNING	

		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Stopping solution A	DANGER	
		
	H314	Causes severe skin burns and eye damage.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER or doctor/physician.
		Sulfuric Acid 1 - 3%
Wash Solution U (20x)	DANGER	
		
	H360	May damage fertility or the unborn child.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
		Boric Acid 0.1 - 0.3%
		Sodium Borate Decahydrate 0.1 - 0.3%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum and lithium heparin plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Within two hours after centrifugation, transfer at least 500 µL of cell-free sample to a storage tube. Tightly stopper the tube immediately.
- Serum and plasma samples may be stored tightly stoppered at 2-8°C, if the assay is to be performed within 48 hours. For longer storage keep frozen (at < -20°C), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted in Sample diluent. For pediatric male samples: Dilute 1 part of sample with 9 parts of Sample diluent before testing.

Use the following guidelines when preparing samples:

- Ensure residual fibrin and cellular matter have been removed prior to analysis.
- Follow blood collection tube manufacturer's recommendations for centrifugation.

Serum and lithium heparin plasma values for 120 samples (serum values ranging from 0.00 to 17.24 ng/mL) were compared using the AMH Gen II ELISA. Results are as follows: [Li-Hep plasma] = 0.951[serum]+0.000; R = 0.995

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

Storage conditions for reagents after dilution are indicated in paragraph Procedure.

Plate: 12 x 8 wells (ready-to-use)

Unused strips have to be stored at 2-8°C in the self-lock bag provided.

Sample diluent: one 13.0 mL bottle (ready-to-use)

The bottle contains buffer with bovine serum albumin (BSA), ProClin 300 (<0.5%) and sodium azide (<0.1%).

Antibody-Biotin conjugate: one 13.0 mL bottle (ready-to-use)

The bottle contains biotinylated anti-AMH antibody in buffer with protein (bovine, mouse), ProClin 300 (<0.3%) and sodium azide (<0.1%).

Streptavidin-Enzyme conjugate: one 13.0 mL bottle (ready-to-use)

The bottle contains streptavidin-HRP in buffer with protein (mouse, fish) and methanol (<10%).

Assay buffer: one 26.0 mL bottle (ready-to-use)

The bottle contains buffer with BSA, protein (bovine, mouse), ProClin 300 (<0.3%) and sodium azide (<0.1%).

Assay buffer (26 mL) may be ordered separately, too (REF. B38561).

TMB Chromogen solution: one 11 mL bottle (ready-to-use)

The bottle contains tetramethylbenzidine (TMB) in citrate buffer with hydrogen peroxide.

TMB Chromogen solution (11 mL) may be ordered separately, too (REF. DSL-10-9755-1).

Wash solution U (20X): one 50 mL vial

Concentrated solution has to be diluted before use. It may be ordered separately, too (REF. A54825).

Stopping solution A: one 11 mL bottle (ready-to-use)

The bottle contains 0.2 M sulfuric acid.

Stopping solution A (11 mL) may be ordered separately, too (REF. C24811).

MATERIALS REQUIRED, BUT NOT PROVIDED

In addition to standard laboratory equipment, the following items are required:

- **AMH Gen II Calibrators and Controls, supplied upon REF. A79766.**
- Tubes (for premix with assay buffer).
- Precision pipette to deliver 10–1,000 µL.
- Orbital microtiter plate shaker.
- Microtiter plate washer (optional).
- Vortex type mixer.
- Absorbent material for blotting strips.
- Microtiter plate reader (450/405 nm and 600-630 nm) (bichromatic reading).

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature and mix them thoroughly by gentle inversion before the use.

Preparation of the wash solution

Pour the content of the vial into 950 mL of distilled water and homogenize. The diluted solution can be stored in a tightly sealed bottle at 18-25°C one month or at 2-8°C until the expiry date of the kit.

Microtitration wells

Select the number of coated wells required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant. The pouch must be resealed to protect from moisture.

Assay procedure

Step 1 Preparation of reagents	Step 2 Additions, 1st incubation	Step 3 2nd incubation
Before adding to the wells, in a tube prepare 1 part of each calibrator, control, or test sample respectively (including diluted pediatric male samples) with 5 parts Assay buffer (for example, 60 µL of calibrator, control, or sample + 300 µL of AMH Gen II Assay Buffer). Mix thoroughly.	Within 1 hour, to coated wells add successively: 120 µL of premixed calibrator, control or sample. Incubate 1 hour at 18-25°C with shaking (600-800 rpm).	Aspirate carefully the contents of each well. Wash 5 times with 400 µL of the wash solution using an automatic microplate washer or manually using a precision pipette. Blot and dry by inverting plate on absorbent material. Add 100 µL of Antibody-Biotin conjugate solution to each well. Incubate 1 hour at 18-25°C with shaking (600-800 rpm).

Step 4 3rd incubation	Step 5 Enzymatic step	Step 6 Reading
Aspirate carefully the contents of each well. Wash 5 times with 400 µL of the wash solution using an automatic microplate washer or manually using a precision pipette. Blot and dry by inverting plate on absorbent material. Add 100 µL of Streptavidin-Enzyme conjugate solution to each well. Incubate 30 minutes at 18-25°C with shaking (600-800 rpm).	Aspirate carefully the contents of each well. Wash 5 times with 400 µL of the wash solution using an automatic microplate washer or manually using a precision pipette. Blot and dry by inverting plate on absorbent material. Add 100 µL of chromogenic substrate to each well.* Incubate 8-12 minutes at 18-25°C with shaking (600-800 rpm).**	Add 100 µL of stop solution to each well.*** Read absorbance within 30 minutes at 450 nm.****

**Avoid exposure to direct sunlight.*

***Be aware that color may develop more quickly or more slowly than the recommended incubation time depending on the localized room temperature. Visually monitor the color development to optimize the incubation time.*

****To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed used to add the TMB chromogenic solution.*

*****If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set between 600-630 nm.*

RESULTS

Results are obtained from the calibrator curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

The results in the quality control department were calculated using *weighted cubic regression* curve fit with ABS on the log vertical axis and analyte concentration of the calibrators on the log horizontal axis.

Other calculation methods may give slightly different results.

Calibrators	AMH (ng/mL)	ABS	ABS/ABS_{max} (%)
0	0	0.028 (blank)	-
1	0.11	0.045	1.50
2	0.33	0.081	2.70
3	1.00	0.173	5.77
4	3.80	0.556	18.5
5	10.0	1.621	54.1
6	25.0	2.999	100

ABS = Absorbance
(Example of standard curve, do not use for calculation).

Samples

For each sample, locate ratio ABS on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

All analytical characteristics are stated in ng/mL. To convert to SI units (International System of Units):
1 ng/mL = 7.14 pM

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from healthy subjects are indicative only.

Samples	n	Median age (years)	Median (ng/mL)	2.5-97.5th Percentile (ng/mL)
Random males	136	38	5.7	1.3-14.8
Random females	95	30	2.4	ND-12.6
Males fertility clinic	100	37	5.3	0.8-14.6
Females 3rd day of cycle	106	-	1.5	ND-10.6
Post menopausal females†	45	71	ND	ND
Boys†	36	4.8	56.3	3.8-159.8
Girls†	36	5.0	1.3	ND-8.9

†Non parametric reference at 90% limit.

QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Sensitivity

Limit of detection (LoD): 0.08 ng/mL

The LoD of the assay is 0.08 ng/mL, determined consistent with guidelines in CLSI document EP17-A2 [5] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 168 blank and 168 low level samples; and Limit of Blank (LoB) of 0.00 ng/mL.

Specificity

The antibodies used in the assay bind to the mature region of AMH, which is more stable against proteolysis compared to pro-hormone region. This highly characterized dual monoclonal antibody pair is specific to AMH and does not detect inhibin A, activin A, FSH and LH at 2 times their physiological concentrations.

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [6]. For repeatability the coefficients of variation were found below or equal to 14.0 % for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 14.7 % for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.08 to 25.28 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

High-concentration samples were serially diluted with sample diluent. The recovery percentages obtained were between 80.5% to 107.5%.

Recovery test

Low-concentration samples were spiked with known quantities of AMH. The recovery percentages obtained were between 82.4% to 111.2%.

Measurement range (from LoD to the highest calibrator): 0.08 to approximately 25.0 ng/mL.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [8, 9, 10].

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

“Hook effect“: there is no hook effect, when the two-step procedure is used [11].

APPENDIX

PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Summary

AMH is a glycoprotein dimer composed of two 72 kDa monomers linked by disulfide bridges [12,13,14,15,16,17,18,19]. It belongs to the transforming growth factor-β family. AMH performs various physiological functions. In males, AMH is secreted by the Sertoli cells. During embryonic development, AMH is responsible for Mullerian duct regression. AMH continues to be produced by the testicles until puberty and then decreases slowly to residual post-puberty values. In females, AMH is produced in small amounts by ovarian granulosa cells after birth until menopause, and then becomes undetectable.

Interference

Serum samples containing AMH concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using AMH Gen II ELISA. Values were calculated as described in CLSI EP07, 3rd ed. [20]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Acetylsalicylic acid	45.80 µg/mL
Ascorbic acid	117.5 µg/mL
Biotin	1,656 ng/mL
Conjugated bilirubin	440.8 µg/mL
Hemoglobin	3,094 µg/mL
Heparin	7,030 ng/mL
Cholesterol	0.69 mg/mL
Ibuprofen	272.8 µg/mL
Prednisone	150.7 ng/mL
Prednisolone	1,415 ng/mL
Rheumatoid factor	53.3 IU/mL
Triglycerides	1.79 mg/mL
Unconjugated bilirubin	166.7 µg/mL

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Precision

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, in triplicates per run. Assays were performed by two lab technicians, by two reagent lots. There were 120 individual measurements per sample with no invalid results.

Serum samples	Mean (ng/mL)	Repeatability		Within-laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
S1	1.17	0.16	14.04	0.17	14.72
S2	2.50	0.18	7.34	0.20	8.11
S3	4.54	0.33	7.17	0.51	11.14
S4	9.37	0.69	7.37	0.83	8.81
S5	15.99	1.61	10.07	2.10	13.13

Li-Hep plasma samples	Mean (ng/mL)	Repeatability		Within-laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
P1	0.51	0.06	11.30	0.09	17.52
P2	1.16	0.11	9.12	0.17	14.84
P3	2.68	0.14	5.12	0.26	9.53
P4	3.90	0.27	7.00	0.36	9.30
P5	7.13	0.45	6.36	0.70	9.76
P6	13.66	1.19	8.70	1.80	13.16

Accuracy

Linearity

The assay demonstrated to be linear from 0.15 to 20.59 ng/mL using lithium heparin plasma samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

Samples were diluted in Sample diluent and assayed according to the assay procedure of the kit.

Serum samples	Dilution factor	AMH (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	5.17	-	-
	1:2	2.56	2.59	99.03
	1:4	1.39	1.29	107.5
	1:8	0.59	0.65	91.30
	1:16	0.26	0.32	80.46
S2	-	11.85	-	-
	1:2	5.71	5.93	96.37
	1:4	2.76	2.96	93.16
	1:8	1.32	1.48	89.11
	1:16	0.69	0.74	93.16
S3	-	11.57	-	-
	1:2	4.80	5.79	82.97
	1:4	2.44	2.89	84.36
	1:8	1.34	1.45	92.65
	1:16	0.66	0.72	91.27

Li-Hep plasma samples	Dilution factor	AMH (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	18.94	-	-
	1:2	9.53	9.47	100.6
	1:4	4.66	4.74	98.42
	1:8	2.22	2.37	93.77
	1:16	1.17	1.18	98.84
P2	-	15.98	-	-
	1:2	8.14	7.99	101.9
	1:4	3.90	4.00	97.62
	1:8	1.95	2.00	97.62
	1:16	1.10	1.00	110.1
P3	-	9.45	-	-
	1:2	4.20	4.73	88.89
	1:4	2.01	2.36	85.08
	1:8	1.14	1.18	96.51
	1:16	0.65	0.59	110.1
P4	-	7.78	-	-
	1:2	3.64	3.89	93.57
	1:4	2.03	1.95	104.4
	1:8	1.09	0.97	112.1
	1:16	0.53	0.49	109.0

Recovery test

Samples were spiked with known quantities of AMH and assayed according to the assay procedure of the kit.

Serum samples	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
S1	0.21	0.11	0.32	0.32	98.68
	0.21	0.24	0.46	0.51	111.2
	0.21	0.48	0.69	0.67	97.71
S2	2.52	0.96	3.48	3.15	90.50
	2.40	2.06	4.47	3.68	82.37
	2.54	5.94	8.49	7.24	85.32
S3	7.24	4.98	12.21	12.17	99.63
	7.07	9.71	16.78	16.51	98.39
	6.75	18.55	25.29	24.19	95.65

Li-Hep plasma samples	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	0.23	0.11	0.34	0.32	93.11
	0.23	0.24	0.48	0.44	92.04
	0.23	0.48	0.70	0.67	95.07
P2	2.32	0.96	3.28	3.02	92.11
	2.21	2.06	4.28	4.31	100.8
	2.34	5.94	8.28	8.21	99.14
P3	8.76	4.98	13.74	13.72	99.88
	8.55	9.71	18.27	16.70	91.42
	8.16	18.55	26.71	24.24	90.76

Method comparison

The AMH Gen II ELISA has been compared to another commercially available AMH kit (Method X). One hundred nineteen male and female serum and lithium heparin plasma samples, ranging in age from 20-50 years were assayed and linear regression analysis of the results yielded the following:

Regression:

A. AMH SERUM = 1.0 (Method X)

(r = 0.98; 97.5% CI = 0.95-0.98, P <0.0001)

B. AMH PLASMA = 0.967 (Method X)
(r = 0.98; 97.5% CI = 0.95-0.98, P <0.0001)

Symbols Key

REF	Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考
IVD	In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / İn Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷
CONTENTS	Contents / Contenu / Inhalt / Contenuto / Contenido / Conteúdo / Περιεχόμενο / 组成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄
	Manufactured by / Fabriqué par / Hergestellt von / Prodotto da / Fabricado por / Tillverkas av / Κατασκευαστής / 制造商 / Gamintojas / Gyártó: / Producent / Výrobce / Výrobca / 제조 / Üretici / Изготовлено / Произведено от / 製造商
Σ	Contains sufficient for <n> tests / Contenu suffisant pour "n" tests / Inhalt ausreichend für <n> Prüfungen / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos / Conteúdo suficiente para "n" ensaios / Räcker till "n" antal tester / Περιεχόμενο επαρκές για "ν" εξετάσεις / 含量足够 <n> 次测试 / Turinio pakanka < n > tyrim / <n> teszthez elegendő mennyiséget tartalmaz / Zawartość wystarcza na <n> testów / Lze použít pro <n> testů / Obsah vystačí na < n > testov / <n> 테스트에 대해 충분한 양 포함 / <n> sayıda test için yeterlidir / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 內容物足夠執行 <n> 次測試
CE	CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / CE 标志 / CE ženklas / CE jelzés / Znak CE / Značka CE / Označenie CE / CE 표시 / CE İşareti / Маркировка CE / CE маркировка / CE 標識
SDS	Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表
	Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明
	Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo/i di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 温度范围 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sıcaklık aralıkları / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明
	Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事项 / Įspėjimas / Figyelem / Uwaga / Upozornění / Upozornenie / 주의 / Dikkat / Внимание / 注意
	Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日
LOT	Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號
	Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

SOLN STOP	Stopping Solution / Solution d'arrêt / Stopperlösung / Soluzione di arresto / Solución de Detención / Solução de paragem / Διάλυμα αναστολής / 终止液 / Stabdymo tirpalas / Leállító oldat / Roztwór zatrzymujący / Roztok pro zastavení / Zastavovací roztok / 정지 용액 / Durdurma Çözeltisi / Завершающий раствор / Разтвор за спиране / 終止溶液
BUF ASSAY	Assay Buffer / Tampon pour le dosage / Assay-Puffer / Tampone per le analisi / Tampón de análisis / Tampão de ensaio / Assay Buffert / Analysebuffer / Määrityspuskuri / Ρυθμιστικό διάλυμα ανάλυσης / Analizės buferinis tirpalas / Assay puffer / Bufor do testu / Tlmivý roztok / Tlumivý roztok / 분석 완충액 / Test Tamponu / Буфер для анализа / Буфер за анализи / 分析緩衝劑 / Soluție tampon analiză / Pufer za test / Test pufer
BIO CONJ CONC	Biotin Conjugate Concentrate / Concentré de conjugué biotine / Biotinkonjugat-Konzentrat / Concentrato del coniugato biotina / Concentrado de conjugado de biotina / Concentrado Conjugado de Biotina / Biotinkonjugat, koncentrat / biotinkonjugatkonsentrat / Biotiinikonjugaatti, konsentraatti / Συμπύκνωμα συζεύγματος βιοτίνης / Biotino konjugato koncentratas / Biotin konjugátum koncentrátum / Koncentrat koniugatu biotyny / Koncentrát konjugátu biotinu / Koncentrát konjugátu biotínu / 비오틴 복합체 농축액 / Biotin Konjugat Konsantresi / Конъюгат биотина, концентрат / Концентрат на конюгат биотин / 濃縮生物素結合物 / Concentrat conjugat biotină / Koncentrat konjugata biotina / Koncentrat biotin konjugata / Biotine conjugaatconcentraat
STREP CONJ	Streptavidin Conjugate / Conjugué de streptavidine / Streptavidinkonjugat/ Coniugato streptavidina / Conjugado de estreptavidina / Streptavidinkonjugat / Σύζευγμα στρεπταβιδίνης / 链霉亲和素酶联物 / Streptavidino konjugatas / Sztreptavidin konjugátum / Koniugat streptawidyny / Konjugat streptavidin / 스트렙타비딘 복합체 / Streptavidin Konjugat / Конъюгат стрептавидина / Стрептавидин конюгат / 鏈霉親和素結合
SOLN TMB	TMB Solution / Solution TMB / TMB-Lösung / Soluzione TMB / Solución de TMB / Solução TMB / TMB-lösning / Διάλυμα TMB / TMB 溶液 / TMB tirpalas / TMB oldat / Roztwór TMB / Roztok TMB /Raztopina TMB / TMB 용액 / TMB Çözeltisi / TMB, раствор / TMB Разтвор / TMB 溶液
SAMPLE DIL	Sample Diluent / Diluant d'échantillons / Probenverdünnungsmittel / Diluente campione / Diluyente de muestras / Diluente de amostras / Provutspädningslösning / Prøve Diluent / Näytteen diluentti / Διαλυτικό δειγμάτων / Mėginio skiediklis / Minta diluens / Rozcieńczalnik próbki / Vzorek redicího roztokus / Riediaci roztok vzorky / 검체 희석액 / Numune Dilüent / Раствор для разведения образцов / Буфер за проба / 樣品稀釋劑 / Rastvor uzorka / Monsterverdunningsmiddel
SOLN WASH 20X	Wash Solution Concentrate 20X / Solution de lavage concentrée 20X / Waschlösungskonzentrat 20X / Concentrato di soluzione di lavaggio 20X / Solución de lavado concentrada 20X / Concentrado de solução de lavagem 20X / Tvättlösningskoncentrat 20X / Συμπυκνωμένο διάλυμα πλύσης 20X / 浓缩清洗液 20X / Plovimo tirpalo koncentratas 20X / 20X mosóoldat-koncentrátum / Koncentrat 20X roztworu płuczącego / Koncentrát mycího roztoku 20X / Koncentrát premývacieho roztoku 20X / 농축 세척액(20배) / Yıkama Çözeltisi Konsantresi 20X / Концентрат промывочного раствора 20X / Концентрат на разтвор за промиване 20X / 清洗溶液濃縮 20X
PLATE	Plate / Plaque / Platte / Piastra / Placa / Platta / Πλάκα / 板 / Plokštelė / Lemez / Płytka / Deska / Doštička / 판 / Plaka / Планшет / Чашка / 滴盤
IFU	Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用說明
	Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biyolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害

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