Instructions for Use

25-OH-Vitamin D direct ELISA

Enzyme immunoassay for the quantitative direct determination of 25-OH-Vitamin D in human serum and plasma.

REF **UK51081**

Σ **12x8**

2-8°C

EU: IVD CE U.S.: *For research use only. Not for use in diagnostic procedures.*

I B L I N T E R N A T I O N A L G M B H
Flughafenstrasse 52a
D-22335 Hamburg, Germany
Phone: +49 (0)40-53 28 91-0
Fax: +49 (0)40-53 28 91-11
IBL@IBL-International.com
www.IBL-International.com

25-Hydroxy Vitamin D EIA

Enzymeimmunoassay for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated metabolites in serum or plasma

Technique immuno-enzymatique pour le dosage de la 25-hydroxyvitamine D et d'autres métabolites hydroxylés dans le sérum ou le plasma

Enzymimmunassay zur quantitativen Bestimmung von 25-Hydroxy-Vitamin D und anderer hydroxylierter Metaboliten in Serum oder Plasma

Dosaggio immunoenzimatico per la determinazione quantitativa della 25-idrossivitamina D e altri metaboliti idrossilati nel siero o plasma

Inmunoensayo enzimático para la determinación cuantitativa de 25-hidroxivitamina D y otros metabolitos hidroxilados en suero o plasma

CE

REF UK51081

Σ 96

Intended Use

For In Vitro Diagnostic Use

The IDS 25-Hydroxy Vitamin D EIA kit is an enzymeimmunoassay intended for the quantitative determination of 25-hydroxyvitamin D (25-OH D) and other hydroxylated metabolites in human serum or plasma. Results are to be used in conjunction with other clinical and laboratory data to assist the clinician in the assessment of vitamin D sufficiency in adult populations.

Summary and Explanation

Vitamin D is a commonly used collective term for a family of closely related seco-steroids. Upon exposure to sunlight, 7-dehydro-cholesterol, located deep in the actively growing layers of the epidermis, undergoes photolytic cleavage of the "B" ring to yield pre-vitamin D_3 which is isomerised to vitamin D_3 (cholecalciferol). Vitamin D_3 and vitamin D_2 (ergocalciferol) may also be obtained by dietary supplementation or from a limited number of foods. Vitamin D_2 is metabolised in a similar way to vitamin D_3.

Vitamin D is stored in adipose tissue and enters the circulation bound to vitamin D binding protein (VDBP) and albumin. In the liver, vitamin D is hydroxylated to give 25-hydroxyvitamin D which also circulates as a complex with VDBP. A small proportion of the 25-OH D is further hydroxylated in the kidney, under direct regulation by parathyroid hormone and ionised calcium levels, to form the biologically-active calcitropic hormone 1,25-di-hydroxyvitamin D. Further hydroxylation and metabolism of vitamin D produces compounds that are water soluble and readily excreted.

Hepatic vitamin D 25-hydroxylase activity is not tightly regulated, and changes in cutaneous production of vitamin D_3, or ingestion of vitamin D (D_3 or D_2), will result in changes in circulating levels of 25-OH D [(1)].

Serum concentration of 25-OH D is considered to be the most reliable measure of overall vitamin D status and thus can be used to determine whether a patient is vitamin D sufficient[(2)]. Assessment of vitamin D status may be required to determine the cause of abnormal serum calcium concentrations in patients.

Method Description

The IDS 25-Hydroxy Vitamin D EIA kit is an enzymeimmunoassay for the quantitation of 25-OH D and other hydroxylated metabolites in serum or plasma. Calibrators, controls and samples are diluted with biotin labelled 25-OH D. The diluted samples are incubated in microtitre wells which are coated with a highly specific sheep 25-OH D antibody for 2 hours at room temperature before aspiration and washing. Enzyme (horseradish peroxidase) labelled avidin, is added and binds selectively to complexed biotin and, following a further wash step, colour is developed using a chromogenic substrate (TMB). The absorbance of the stopped reaction mixtures are read in a microtitre plate reader, colour intensity developed being inversely proportional to the concentration of 25-OH D.

Warnings and Precautions

The IDS 25-Hydroxy Vitamin D EIA kit is for in vitro diagnostic use only and is not for internal use in humans or animals. This product must be used strictly in accordance with the instructions set out in the Package Insert. IDS Limited will not be held responsible for any loss or damage (except as required by statute) howsoever caused, arising out of non-compliance with the instructions provided.

CAUTION: this kit contains material of human and/or animal origin. Handle kit reagents as if capable of transmitting an infectious agent.

Appropriate precautions and good laboratory practices must be used in the storage, handling and disposal of the kit reagents. Disposal of kit reagents should be in accordance with local regulations.

Human serum: Calibrators CAL and Controls CTRL Human material used in the preparation of this product has been tested by FDA recommended assays for the presence of antibody to Human Immunodeficiency Virus (HIV I and II), Hepatitis B surface antigen, antibody to Hepatitis C, and found negative. As no test can offer complete assurance that infectious agents are absent, the reagents should be handled in accordance at Biosafety Level 2.

Sodium azide

Xn. Harmful: Controls CTRL contain sodium azide (NaN_3) >0.1% (w/w) (<1%).

R22 Harmful if swallowed.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S46 If swallowed, seek medical advice immediately and show this container or label.

S36/37 Wear suitable protective clothing and gloves.

S60 This material and/or its container must be disposed of as hazardous waste.

Some reagents in this kit contain sodium azide as a preservative, which may react with lead, copper or brass plumbing to form highly explosive metal azides. On disposal, flush with large volumes of water to prevent azide build up.

0.5M hydrochloric acid

Stop Solution HCL contains 0.5M hydrochloric acid.

R36/38 Irritating to eyes and skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37 Wear suitable protective clothing and gloves.

Tetramethylbenzidine

TMB Substrate SUBS contains 3,3',5,5'-tetramethylbenzidine.

R21/22 Harmful by contact with skin and if swallowed.

S36/37 Wear suitable protective clothing and gloves.

Preparation of Reagents

Controls CTRL: Controls CTRL are supplied lyophilised. Reconstitute with 1 mL of distilled or deionised water, replace stopper and stand for 10-15 minutes at room temperature. Invert several times to ensure complete reconstitution. Store at 2-8°C.

25-D Biotin Solution 25-D BIOTIN SOLN: 25-D Biotin Concentrate 25-D BIOTIN 50x is supplied lyophilised. Add 3 mL of Buffer BUF to the bottle of lyophilised 25-D Biotin Concentrate 25-D BIOTIN 50x (blue colour). Replace the stopper and stand for 10-15 minutes at room temperature. Invert several times to ensure complete reconstitution. Add the reconstituted 25-D Biotin Concentrate 25-D BIOTIN 50x (3 mL) back into the bottle containing the remaining Buffer BUF. Mix well by inversion. The 25-D Biotin Solution (50 mL) is green in colour. Mark the bottle "25-D Biotin Solution". Store at 2-8°C.

Wash Solution WASHBUF SOLN: Add the contents of each bottle of Wash Concentrate WASHBUF 20x to 950 mL of distilled or de-ionised water and mix. Store at room temperature.

All other reagents are supplied ready for use.

Allow all reagents to come to room temperature before use.

Reagents should be mixed by repeated inversion before use in the assay.

Shelf Life and Storage of Reagents

This kit is stable until the stated expiry date if stored as specified. Upon receipt, store all reagents at 2-8°C.

Reconstituted Controls CTRL and 25-D Biotin Solution 25-D BIOTIN SOLN can be stored at 2-8°C for up to 8 weeks.

Unused Antibody Coated Plate MICROPLAT strips must be returned to the foil pouch with the desiccant sachet. Fold over the end of the foil pouch and seal in one of the plastic selfseal bags provided. Store at 2-8°C for up to 8 weeks.

Wash Solution WASHBUF SOLN can be stored at room temperature for up to 8 weeks.

Indications of possible deterioration of kit reagents

The presence of abnormal particulate matter in any of the reagents.

A decrease in the absorbance of the zero calibrator.

A shift in the slope of the curve from its normal position.

Specimen Collection and Storage

The assay should be performed using serum or plasma (EDTA or heparin) specimens. Specimens should be separated as soon as possible after collection. For long term storage, store at -20°C. Avoid repeated freeze/thaw of samples.

Procedure

Materials Provided

1. **CAL 0 - 6 – Calibrators (REF AC-5701A - AC-5701G):**
   Buffered human serum containing 25-hydroxyvitamin D and <0.09% sodium azide. The exact value of each Calibrator is printed on the QC Report, 1 mL per bottle, 7 bottles per kit.

2. **MICROPLAT - Antibody Coated Plate (REF AC-5702W):**
   Microplate with 25-hydroxyvitamin D sheep polyclonal antibody linked to the inner surface of the polystyrene wells, 12 x 8 well strips in a foil pouch with desiccant.

3. **25-D BIOTIN 50x - 25-D Biotin Concentrate (REF AC-5703):**
   Lyophilised buffer containing 25-hydroxyvitamin D labelled with biotin, and proprietary stabilisers, 1 mL per bottle. 1 (F1) or 2 (F2) bottles per kit.

4. **BUF - Buffer (REF AC-5703B):**
   Proprietary reagent for dissociating 25-hydroxyvitamin D from binding proteins, 50 mL per bottle. 1 (F1) or 2 (F2) bottles per kit.

5. **ENZYMCONJ - Enzyme Conjugate (REF AC-5704):**
   Phosphate buffered saline containing avidin linked to horseradish peroxidase, protein, enzyme stabilisers and preservative. 22 mL per bottle. 1 (F1) or 2 (F2) bottles per kit.

6. **CTRL 1 - 2 – Controls (REF AC-5705A - AC-5705B):**
   Lyophilised human serum containing 25-hydroxyvitamin D and <1% sodium azide (0.09% reconstituted), 1 mL per bottle, 2 bottles per kit.

7. **SUBS - TMB Substrate (REF AC-SUBS):**
   A proprietary aqueous formulation of tetramethylbenzidine (TMB) and hydrogen peroxide, 28 mL per bottle. 1 (F1) or 2 (F2) bottles per kit.

8. **HCL - Stop Solution (REF AC-STOP):**
   0.5M Hydrochloric Acid, 13 mL per bottle. 1 (F1) or 2 (F2) bottles per kit.

9. **WASHBUF 20x - Wash Concentrate (REF AC-WASHL):**
   Phosphate buffered saline containing Tween, 50 mL per bottle.

10. **Adhesive Plate Sealer**
    8 per kit.

11. **Documentation**
    Package Insert and QC report.

Materials Required but not Provided

1. Disposable 12 x 75 mm borosilicate glass or polypropylene tubes.
   Note: polystyrene tubes are not suitable. Do not reuse tubes.
2. Precision pipetting devices to deliver 25 µL and 200 µL.
3. Repeating pipettes to deliver 1 mL, e.g. Eppendorf Multipipette 4780, or similar.
4. Precision multi-channel pipettes to deliver 100 µL and 200 µL.
5. Vortex mixer.
6. Automatic microplate washer (optional).
7. Photometric microplate reader and data analysis equipment.

Assay Procedure

Reconstitute or prepare reagents as described in "Preparation of Reagents".

1. Prepare labelled borosilicate glass or polypropylene tubes, one for each Calibrator [CAL], Control [CTRL] and sample [SPE].
2. Add **25 µL** of each Calibrator [CAL], Control [CTRL] or sample to the appropriately labelled tubes.
3. Add **1 mL** of 25-D Biotin Solution [25-D BIOTIN] [SOLN] to all tubes. Vortex thoroughly for 10 seconds.
4. Add **200 µL** of each diluted Calibrator, Control or sample to the appropriate wells of the Antibody Coated Plate [MICROPLAT] in duplicate.
   Cover the plate with an adhesive plate sealer. Incubate at 18-25°C for 2 hours.
5. Wash all wells three times with Wash Solution [WASHBUF] [SOLN].
   a) Automatic plate wash: Set plate washer to dispense at least 300 µL of Wash Solution [WASHBUF] [SOLN] per well. Fill and aspirate for 3 cycles.
   b) Manual wash: Decant the contents of the wells by inverting sharply. Dispense 250 µL of Wash Solution [WASHBUF] [SOLN] to all wells. Decant and repeat twice.

   Tap the inverted plate firmly on absorbent tissue to remove excess Wash Solution [WASHBUF] [SOLN] before proceeding to the next step.
6. Add **200 µL** of Enzyme Conjugate [ENZYMCONJ] to all wells using a multichannel pipette.
   Cover the plate with an adhesive plate sealer. Incubate at 18-25°C for 30 minutes.
7. Repeat wash step 5.
8. Add **200 µL** of TMB Substrate [SUBS] to all wells using a multichannel pipette.
   Cover the plate with an adhesive plate sealer. Incubate at 18-25°C for 30 minutes.

   Note: TMB Substrate is easily contaminated. Only remove the required amount for the assay from the bottle. Dispose of unused TMB Substrate. Do not return to bottle.
9. Add **100 µL** of Stop Solution [HCL] to all wells using a multichannel pipette.
10. Measure the absorbance of each well at 450 nm (reference 650 nm) using a microplate reader within 30 minutes of adding the Stop Solution.

Calibration

25-OH D Calibrators are standardised using U.V. quantification.

Quality Control

The regular use of control samples at several analyte levels is advised to ensure day-to-day validity of results. Two kit controls are provided. The controls should be tested as unknowns. Quality Control charts should be maintained to follow the assay performance.

Calculation of Results

Calculate the percent binding (B/Bo%) of each calibrator, control and unknown sample as follows:

$$B/Bo\% = \frac{\text{(mean absorbance)}}{\text{(mean absorbance for '0' calibrator)}} \times 100$$

Prepare a calibration curve on semi-log graph paper by plotting B/Bo% on the ordinate against concentration of 25-hydroxyvitamin D on the abscissa. Calculate B/Bo% for each unknown sample and read values off the curve in nmol/L (nM).

Alternative data reduction techniques may be employed but users should confirm that the selected curve fit is appropriate and gives acceptable results. Smoothed spline or 4PL curve fits are recommended.

Conversion of Units:

$$X \text{ nmol/L} \quad \overset{\times 0.40 \Rightarrow}{\underset{\Leftarrow \times 2.5}{}} \quad Y \text{ ng/mL}$$

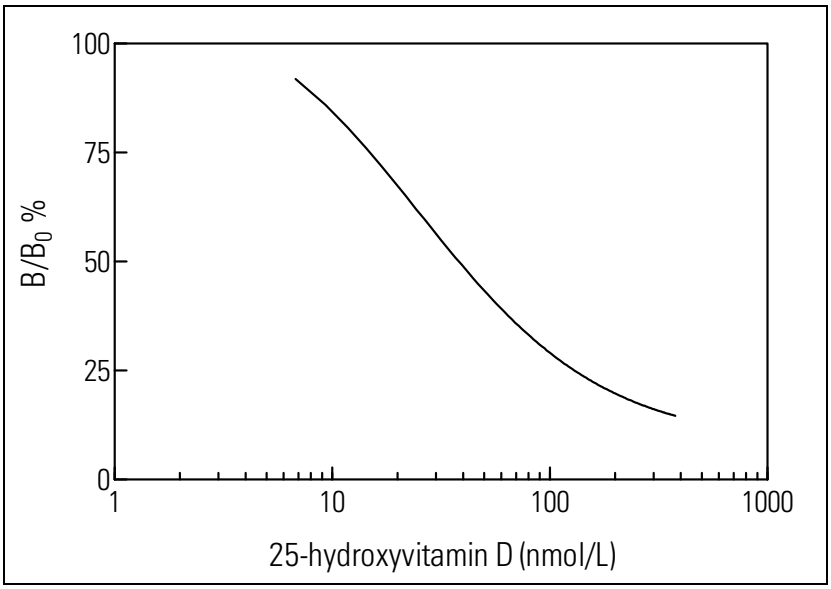
Sample Assay Data

This data is for illustration only and must not be used for the calculation of any sample result.

Well	Description	Abs.	Mean Abs.	B/Bo%	Result (nmol/L)
A1, A2	Calibrator 0 0 nmol/L	2.476 2.530	2.503		
B1, B2	Calibrator 1 6.8 nmol/L	2.313 2.288	2.301	91.9	
C1, C2	Calibrator 2 14 nmol/L	1.912 1.908	1.910	76.3	
D1, D2	Calibrator 3 27 nmol/L	1.495 1.499	1.497	59.8	
E1, E2	Calibrator 4 67 nmol/L	0.919 0.905	0.912	36.4	
F1, F2	Calibrator 5 179 nmol/L	0.521 0.522	0.522	20.8	
G1, G2	Calibrator 6 380 nmol/L	0.372 0.368	0.370	14.8	
H1, H2	Sample 1	1.237 1.257	1.247	49.8	39
A3, A4	Sample 2	0.951 0.969	0.960	38.4	62
B3, B4	Sample 3	0.591 0.612	0.602	24.0	138

Typical Calibration Curve

This sample calibration curve is for illustration only.



Limitations of Use

1. Samples suspected of containing analyte concentrations in excess of the highest calibrator should be assayed in dilution.
2. As in the case of any diagnostic procedure results must be interpreted in conjunction with the patient's clinical presentation and other information available to the physician.
3. The performance characteristics of this assay have not been established in a paediatric population.
4. In rare cases, interference due to extremely high titres of antibodies to avidin can occur.
5. The following substances have been tested and found not to interfere in the IDS 25-Hydroxy Vitamin D assay:

Haemoglobin	tested up to 1470 mg/dL
Bilirubin	tested up to 513 µmol/L
Lipid	tested up to 5.6 mmol/L triglyceride

Expected Values

Each laboratory should determine ranges for their local population.

There is no universal agreement on the optimal concentration of 25-OH D. Ranges should be based on clinical decision values that apply to both sexes of all ages rather than population based reference ranges for 25-OH D. To that end, a large study examined the relationship of intact PTH with vitamin D levels in serum. A plateau for iPTH was seen at ~30 ng/mL[3]. Similarly, Calcium (Ca) absorption increased with increasing 25-OH D level until ~30 ng/mL 25-OH D was reached. Optimal Ca absorption requires levels of 25-OH D exceeding 30 ng/mL[4].

In the case of 25-OH D, there are also many other factors that may influence values: diet, time of day, sun exposure, season of year[5], geographic location[6], age[7], use of sunscreen and/or protective clothing[8,9] and skin pigmentation[10]. Thus, sampling a group of apparently healthy individuals is not the ideal way to establish the reference range.

The US National Osteoporosis Foundation recommends a level >30 ng/mL to protect bone health[11]. Similarly, the US National Kidney Foundation considers levels <30 ng/mL to be insufficient or deficient[12].

From a review of the available literature, the recommendations for 25-OH D levels are:

	Range	
Level	**nmol/L**	**ng/mL**
Deficient	<25	<10
Insufficient	25-74	10-29
Sufficient	75-250	30-100
Potential Intoxication	>250	>100

The following range has been determined using the IDS 25-Hydroxy Vitamin D EIA kit and is provided for guidance only. Each laboratory should determine ranges for their local population.

Normal adults 47.7 - 144 nmol/L (n = 36)

Performance Data

Accuracy

The IDS 25-Hydroxy Vitamin D EIA kit was compared against a recognised radioimmunoassay for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated metabolites. A population of 180 samples, selected to represent a wide range of 25-hydroxyvitamin D [9.3 - 151.2 nmol/L], were assayed by each method. Least squares regression analysis was performed on the comparative data: IDS = 1.01(x) + 0.7; correlation coefficient (r) = 0.9

Sensitivity

The sensitivity, defined as the concentration corresponding to the mean minus 2 standard deviations of 10 replicates of the zero calibrator, is 5 nmol/L.

Precision

Intra assay mean (nmol/L)	n=10 % CV	Inter assay mean (nmol/L)	n=11 % CV
39.0	5.3	40.3	4.6
67.1	5.6	72.0	6.4
165	6.7	132	8.7

Recovery

Recovery was assessed by adding 25-OH D to samples prior to assay.

Sample	Measured (nmol/L)	Expected (nmol/L)	Recovery %
A	122	126	97
A	95.6	98.4	97
B	147	141	104
B	123	118	105
		Mean	**101**

Linearity

Linearity was assessed by diluting samples with buffer (PBS containing 9%BSA) prior to assay.

Sample	Measured (nmol/L)	Expected (nmol/L)	% M/Exp
A	83.9		
A/2	41.0	42.0	98
A/4	20.8	21.0	99
A/8	13.1	10.5	125
B	83.9		
B/2	43.5	42.0	104
B/4	23.1	21.0	110
B/8	10.7	10.5	102
C	104		
C/2	45.9	52.0	88
C/4	22.5	26.0	87
C/8	14.1	13.0	108
		Mean	**102**

Specificity

The specificity of the antiserum was assessed with the following analytes at 50% binding of the zero calibrator.

Analyte	Cross-Reactivity
25-Hydroxyvitamin D_3	100%
25-Hydroxyvitamin D_2	75%
24,25-Dihydroxyvitamin D_3	$\geq$100%
Cholecalciferol (D_3)	<0.01%
Ergocalciferol (D_2)	<0.30%

References • Bibliographie • Literatur • Riferimenti bibliografici • Bibliografía

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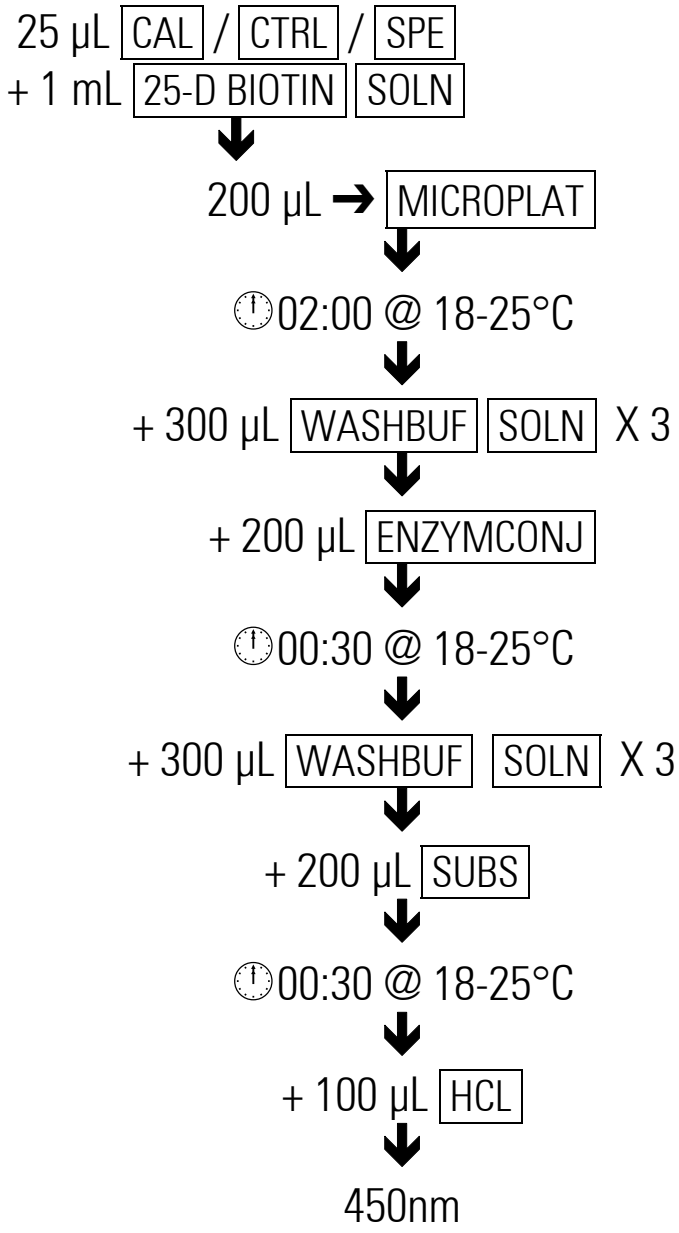
	GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Use By* *Verwendbar bis* *Fecha de caducidad* *Utilizzare entro* *Utiliser jusque* *Houdbaar tot* *Holdbar til* *Použitelné do* *Použiteľné do* *Ημερομηνία λήξης* *Prazo de validade* *Felhasználható* *Använd före* *Użyć przed*		GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Batch code* *Chargenbezeichnung* *Código de lote* *Codice del lotto* *Code du lot* *Lot nummer* *Lotnummer* *Číslo šarže* *Číslo šarže* *Αριθμός Παρτίδας* *Código do lote* *Sarzsszám* *Lot nummer* *Kod partii*
	GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Catalogue number* *Bestellnummer* *Número de catálogo* *Numero di catalogo* *Référence du catalogue* *Catalogus nummer* *Katalognummer* *Katalogové číslo* *Katalógové číslo* *Αριθμός καταλόγου* *Referência de catálogo* *Katalógusszám* *Katalognummer* *Numer katalogowy*		GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Manufacturer* *Hersteller* *Fabricante* *Fabbricante* *Fabricant* *Fabrikant* *Producent* *Výrobce* *Výrobca* *Κατασκευαστής* *Fabricante* *Gyártó* *Tillverkare* *Producent*
	GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Contains sufficient for <n> tests* *Inhalt ausreichend für <n> Prüfungen* *Contenido suficiente para <n> ensayos* *Contenuto sufficiente per "n" saggi* *Contenu suffisant pour "n"tests* *Inhoud voldoende voor "n" testen* *Indeholder tilstrækkeligt til "n" test* *Lze použít pro <n> testů* *Obsah postačuje na <n> stanovení* *Περιεχόμενο επαρκές για «ν» εξετάσεις* *Conteúdo suficiente para "n" ensaios* *A doboz tartalma <n> vizsgálat elvégzéséhez elegendő* *Räcker till "n" antal tester* *Wystarczy na wykonanie <n> testów*		GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*In Vitro Diagnostic Medical Device* *In-Vitro-Diagnostikum* *Producto sanitario para diagnóstico in vitro* *Dispositivo medico-diagnostico in vitro* *Dispositif médical de diagnostic in vitro* *Medisch hulpmiddel voor in-vitro diagnostiek* *Medicinsk udstyr til in vitro-diagnostik* *In Vitro diagnostický zdravotnický prostředek* *Zdravotnícka pomocka in vitro* *In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν* *Dispositivo médico para diagnóstico in vitro* *In vitro diagnosztikum* *Medicintekniska produkter för in vitro diagnostik* *Wyrób do diagnistyki In Vitro*
	GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Temperature limitation* *Temperaturbegrenzung* *Límite de temperatura* *Limiti di temperatura* *Limites de température* *Temperatuurlimiet* *Temperaturbegrænsning* *Teplotní rozmezí od do* *Teplotné rozmedzie od do* *Περιορισμοί θερμοκρασίας* *Limites de temperatura* *Hőmérséklettartomány* *Temperaturbegränsning* *Przestrzegać zakresu temperatury*		GB DE ES IT FR NL DK CZ SK GR PT HU SE PL	*Consult Instructions for Use* *Gebrauchsanweisung beachten* *Consulte las instrucciones de uso* *Consultare le istruzioni per l'uso* *Consulter les instructions d'utilisation* *Raadpleeg de gebruiksaanwijzing* *Se brugsanvisning* *Viz návod k použití* *Viď návod na pužitie* *Συμβουλευτείτε τις οδηγίες χρήσης* *Consulte as instruções de utilização* *Nézze meg a Használati utasítást* *Se handhavandebeskrivningen* *Sprawdź w instrukcji obsługi*

Procedure Summary
Résumé du procédé
Zusammenfassung des Testablaufes
Procedura
Resumen del procedimiento



Immunodiagnostic Systems Ltd (IDS Ltd).
UK Immunodiagnostic Systems Ltd (IDS Ltd), 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD
Tel: +44 (0) 191 519 0660 • Fax: +44 (0) 191 519 0760 • e-mail: info.uk@idsplc.com • www.idsplc.com
USA Immunodiagnostic Systems Inc (IDS Inc.), P.O. Box 17063, Fountain Hills, AZ 85269-7063
Tel: 480-836-7435 • Fax: 480-836-7437 • e-mail: info.us@idsplc.com • www.idsplc.com
Germany Immunodiagnostic Systems GmbH (IDS GmbH), Mainzer Landstrasse 49, 60329 Frankfurt am Main
Tel: +49 (0) 69 3085-5025 • Fax: +49 (0) 69 3085-5125 • e-mail: info.de@idsplc.com • www.idsplc.com
France Immunodiagnostic Systems EURL (IDS EURL), 55 rue Sainte Anne, 75002 PARIS
Tel: +33 (0)1 42 44 12 63 • Fax: +33 (0)1 42 44 40 76 • e-mail: info.fr@idsplc.com • www.idsplc.com
Scandinavia Immunodiagnostic Systems Nordic a/s (IDS Nordic a/s), Marielundvej 30, 2. Sal, 2730 Herlev, Denmark
Tel:+45 44 84 0091 • Fax:+45 44 84 0092 • email: info.nordic@idsplc.com • www.idsplc.com