BioVendor Group

ENG

Product Data Sheet:

TESTOSTERONE FREE IN SALIVA ELISA

Catalogue number:
RTC017R

For research use only!

BioVendor R&D

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CONTENTS

1. INTENDED USE

An enzyme immunoassay for the quantitative determination of testosterone in human saliva.

The assay is intended for in-vitro diagnostic use by professional users only. All therapeutic consequences must take not only the test result but always also all clinical and laboratory diagnostic results into account. The laboratory values themselves must never be the sole reason for therapeutic consequences derived from them. Manual processing is recommended. The usage of laboratory automats is the user's sole responsibility. The kit is intended for single use only

2. STORAGE, EXPIRATION

When stored at 2-8°C unopened reagents will be stable until expiration date. Do not use reagents beyond this date. Opened reagents must be stored at 2-8°C. After first opening the reagents are stable for 30 days if used and stored properly. Keep away from heat and direct sunlight.

Microtiter wells must be stored at 2-8°C. Take care that the foil bag is sealed tightly.

3. INTRODUCTION

At present, the majority of steroid hormone determinations are conducted from serum samples, even if results in the low or very low concentration range are expected, for example, in elderly patients. This is a challenge for any diagnostic laboratory as shown by Taieb et al. in 2003 [9] and others [8]. There has been an official position statement of the Endocrine Society [13] stating that reliable testosterone measurements in serum need either an extraction step or have to be done by chromatographic methods like Tandem MS or GCMS. There now is sufficient evidence that the commercial testosterone assays are unable to quantify low concentrations in a reliable way.

Another major problem associated with the measurement of free hormone levels from serum is the episodic secretion pattern of steroid hormones. Even in 1973 [1] it could be shown that steroid secretion shows a significant episodic pattern. Nevertheless, the majority of the determinations are still made from just one serum sample, resulting in non-reproducible values due to the biological variation. In general, serum measurements can only give the total steroid hormone concentration, whereas saliva testing results in the measurement of the free active hormone fraction [2-4].

So far, all attempts for a direct quantification of free testosterone in serum or plasma samples by commercial immunoassays have failed [6].

Taking into consideration the above mentioned drawbacks of the current analytical procedures, salivary testing seems to be a reliable alternative. It has been shown in the literature [2, 4, 12, 14] that the measurement of free salivary testosterone gives clinically valid results even in the low concentration range. In salivary testing it is easy to compensate for the episodic secretion pattern provided multiple sampling is done (preferably five samples within two hours). The measurement of free testosterone is done with a mixture of these five samples. In contrast to this, measurements from just one single saliva sample always will give arbitrary results (like in serum).

Measurement of salivary testosterone is used as an adjunct in the diagnosis of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females hirsutism (excessive hair) and virilization (masculinization) due to polycystic ovaries, and adrenogenital syndromes. Salivary testosterone further permits a good non-invasive characterization of pubertal maturation stages [15].

4. TEST PRINCIPLE

The Biovendor Testosterone free in Saliva ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the competition principle. An unknown amount of antigen present in the sample and enzymelabeled antigen compete for the binding sites of antibodies coated onto the wells. After incubation, the unbound conjugate is washed off. The amount of bound peroxidase conjugate is inversely proportional to the concentration of testosterone in the sample. After addition of the substrate solution, the intensity of color developed is inversely proportional to the concentration of testosterone in the sample. The enzymatic reaction is stopped by addition of stop solution and the optical density (OD) is measured. A standard curve is constructed by plotting OD values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.

5. PRECAUTIONS

1. This kit is for in-vitro diagnostic use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. The microplate contains break apart strips. Unused wells must be stored at 2-8°C in the sealed foil pouch and used in the frame provided.
4. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
5. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing substrate solution that had previously been used for conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
6. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
7. Do not let wells dry during assay; add reagents immediately after completing the washing steps.
8. Allow the reagents to reach room temperature (18-25°C) before starting the test. Temperature will affect the absorbance readings of the assay.
9. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
10. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
11. Wear disposable protective gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
12. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
13. Do not use reagents beyond expiry date as shown on the kit labels.
14. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiter plate readers.
15. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may be slightly different.
16. Avoid contact with Stop Solution. It may cause skin irritation and burns.
17. Some reagents contain Proclin 300, CMIT and MIT as preservatives. In case of contact with eyes or skin, flush immediately with water
18. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
19. For information on hazardous substances included in the kit please refer to Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from BioVendor.
20. All serious incidents occurring in relation to products made available on the EU market in accordance with Article 2(61) of Regulation (EU) 2017/746 shall be notified to the manufacturer and to the competent authority of the Member State where the user or patient is established in accordance with Article 82 of Regulation (EU) 2017/746.
21. If product information, including labeling, is incorrect or inaccurate, please contact the kit manufacturer or supplier.

6. REAGENT SUPPLIED

1. **Microtiterplate**, (12x8 (break apart) strips, 96 wells;
   Wells coated with an anti-Testosterone antibody (rabbit polyclonal antibody).

2. **Calibrator 0;** 1 vial, 3 ml, ready to use;

3. **Calibrators (Calibrator 1-5),** 5 vials, 1 ml each, ready to use;
   Containing defined concentration of testosterone in buffer solution.
   Concentrations: 10 – 30 – 100 – 300 – 1000 pg/ml

   Conversion: Testosterone (pg/ml) x 3.47 = pmol/l.

4. **Control (1) LOW; Control (2) HIGH** 2 vials, 1 ml each, ready to use;
   Containing defined concentration of testosterone in buffer solution
   For control values and ranges please refer to Quality Control Sheet..

5. **Enzyme Conjugate**, 1 vial, 12 ml, ready to use;
   Testosterone conjugated to horseradish peroxidase;
   Containing <0.01% CMIT/MIT and <0.02% MIT

6. **Substrate Solution**, 1 vial, 22 ml, ready to use;
   Contains tetramethylbenzidine (TMB).

7. **Stop Solution**, 1 vial, 7 ml, ready to use;
   contains 2 N Hydrochloric Acid solution.
   Avoid contact with the stop solution. It may cause skin irritations and burns.

8. **Wash Solution**, 1 vial, 50 ml (10X concentrated);
   see „Preparation of Reagents“.

7. MATERIAL REQUIRED BUT NOT SUPPLIED

- A microtiter plate reader capable for endpoint measurement at 450 nm
- Calibrated variable precision micropipettes and multichannel pipettes with disposable pipette tips
- Microtiter plate mixer operating at 900 rpm
- Manual or automatic equipment for microtiter plate washing
- Absorbent paper
- Deionized water
- Timer
- Semilogarithmic graph paper or software for data reduction
- Vortex mixer
- Microcentrifuge

8. PREPARATION OF REAGENTS

Allow the reagents and the required number of wells to reach room temperature (18-25°C) before starting the test.

Preparation of Wash Solution

Dilute 50 ml of 10X concentrated Wash Solution with 450 ml deionized water to a final volume of 500 ml. The diluted Wash Solution is stable for at least 12 weeks at room temperature (18-25°C). Precipitates may form when stored at 2-8°C, which should dissolve again by swirling at room temperature (18-25°C). The Wash Solution should only be used when the precipitates have completely dissolved.

8.1 Disposal of the kit

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheet.

8.2 Damaged Test Kits

In case of any severe damage to the test kit or components, BioVendor has to be informed in writing, at the latest, one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

9. SPECIMEN COLLECTION AND STORAGE INSTRUCTIONS

9.1 Specimen

Samples containing sodium azide should not be used in the assay. The saliva samples should be completely colorless. Even the slightest red color shows blood contamination. Blood contamination will give falsely elevated concentration values. In case of visible blood contamination, the patient should discard the sample, rinse the sampling device with water, wait for 10 minutes and take a new sample.

9.2 Specimen Collection

For the correct collection of saliva we are recommending to use appropriate devices made from ultra-pure polypropylene. Do not use any PE devices for sampling to avoid significant interferences. Do not use Salivette tubes for sampling. Glass tubes can be used as well, but in this case, special attention is necessary for excluding any interference caused by the stoppers. For more details, please contact BioVendor.

As the testosterone secretion in saliva as well as in serum shows an obvious episodic secretion pattern it is important to care for a proper timing of the sampling. In order to avoid arbitrary results we are recommending to collect 5 samples within a period of two hours (multiple sampling) preferably in the early morning of a normal day directly after waking up. As food might contain significant amounts of steroid hormones samples preferably should be taken while fasting. If fasting should be a problem the collection period should be timed just before lunch or before dinner. In the early morning Testosterone levels of males are significantly higher compared to those ones during the day. The Testosterone concentration in the morning is roughly twice as high compared to the evening concentration.

Do not chew anything during the sampling period. Any pressure to the teeth may result in falsely elevated measurements due to an elevated content of gingival liquid in the saliva sample.

9.3 Specimen Storage and Preparation

Saliva samples may be stored at 2-8°C for up to one week. For longer storage, it is recommended to store the samples at ≤-20°C. Repeated thawing and freezing is not a problem, however this should be avoided to a minimum. Each sample has to be frozen, thawed, and centrifuged at least once anyhow in order to separate the mucins by centrifugation. Upon arrival of the samples at the lab, the samples have to be kept frozen at least overnight. Next morning the samples are thawed and mixed carefully. The samples have to be centrifuged for 5 to 10 minutes. The clear colourless supernatant is easy to pipette. If the sample should show even a slighty red colour, it should be discarded. Blood contamination might influence the results and leads to false results. Due to the episodic variations of the steroid secretion we highly recommend the strategy of multiple sampling. If such a set of multiple samples has to be tested the staff of lab (after at least one freezing, thawing, and centrifugation cycle) should mix aliquots of the 5 single samples and perform the determination using the mixture.

9.4 Specimen Dilution

Samples expected to contain testosterone concentrations higher than the highest calibrator (1000 pg/ml) should be diluted with the zero calibrator before assay. The additional dilution step has to be taken into account for the calculation of the result.

10. ASSAY PROCEDURE

- All reagents and specimens must be allowed to come to room temperature (18-25°C) before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination.
- Optical density is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.
- Respect the incubation times as stated in this instructions for use.
- Calibrators, controls, and samples should at least be assayed in duplicates.
- Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or a multistepper, respectively, or an automatic microtiter plate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with wash solution, and that there are no residues in the wells.
- A calibrator curve must be established for every run.

1. Prepare a sufficient number of microplate wells to accommodate calibrators, controls and patient samples.
2. Dispense 100 µl of each calibrator, control and sample with new disposable tips into appropriate wells
3. Dispense 100 µl of Enzyme Conjugate into each well.
4. Incubate for 60 minutes at room temperature (18-25°C) on a Microtiter plate mixer (900 rpm). Important Note:
   Optimal reaction in this assay is markedly dependent on shaking of the Microtiter plate!
5. Discard the content of the wells and rinse the wells 4 times with diluted Wash Solution (300 µl per well).
   Remove as much Wash Solution as possible by beating the Microtiter plate on absorbent paper.
6. Add 200 µl of Substrate Solution to each well.
7. Incubate for 30 minutes at room temperature (18-25°C) without shaking in the dark.
8. Stop the reaction by adding 50 µl of Stop Solution to each well.
9. Determine the optical density of each well at 450 nm. It is recommended to read the wells within 15 minutes.

11. CALCULATIONS

1. Calculate the average optical density values for each set of calibrators, controls and patient samples.
2. The obtained optical density of the standards (y-axis, linear) are plotted against their corresponding concentrations (x-axis, logarithmic) either on semi logarithmic paper or using an automated method.
3. Using the mean optical density value for each sample determine the corresponding concentration from the standard curve.
4. Automated method: The results in the IFU have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred calculation method. Other data reduction functions may give slightly different results.
5. The concentration of the samples can be read directly from this standard curve. Samples with concentrations higher than that of the highest calibrator have to be further diluted. For the calculation of the concentrations this dilution factor has to be taken into account.

Conversion to SI units:

Testosterone (pg/ml) x 3.47 = pmol/l

Example of Typical Calibrator Curve

Following data are intended for illustration only and should not be used to calculate results from another run.

Calibrator	Optical Density (450nm)
Calibrator 0 (0 pg/ml)	2.869
Calibrator 1 (10 pg/ml)	2.689
Calibrator 2 (30 pg/ml)	2.209
Calibrator 3 (100 pg/ml)	1.353
Calibrator 4 (300 pg/ml)	0.713
Calibrator 5 (1000 pg/ml)	0.338

12. QUALITY CONTROL

Good laboratory practice requires that controls should be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance

It is recommended to use control samples according to national regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels. The kit control values and the corresponding results are stated in the QC certificate added to the kit. The values and ranges stated at the QC sheet always refer to the current kit lot and should be used for direct comparison of the results.

It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results. Employ appropriate statistical methods for analyzing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials patient results should be considered invalid. In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods. After checking the above mentioned items without finding any error contact your distributor or BioVendor

13. LIMITATIONS

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the package insert instruction and with adherence to good laboratory practice. Any improper handling of samples or modification of this test might influence the results.

13.1 Interfering Substrances

- Blood contamination in saliva samples will affect results, and usually can be seen by eye. In case of visible blood contamination, the patient should discard the sample, rinse the sampling device with water, wait for 10 minutes and take a new sample.
- Samples containing sodium azide should not be used in the assay. This can cause false results.
- The result of any immunological test system may be affected by heterophilic antibodies, anti-species antibodies or rheumatoid factors present in human samples (17-19). For example, the presence of heterophilic antibodies in patients who are regularly exposed to animals or animal products may interfere with immunological tests. Therefore, interference with this in vitro immunoassay cannot be excluded. If unplausible results are suspected, they should be considered invalid and verified by further testing. For diagnostic purposes, results should always be considered only in conjunction with the patient's clinical picture and further diagnostic tests.

13.2 Drug Interference

Any medication (cream, oil, pill, etc.) containing testosterone of course will significantly influence the measurement of this analyte. The clinical significance of the determination of testosterone can be invalidated if the patient was treated with natural or synthetic steroids. Any medication should be taken into account when assessing the results.

13.3. High-Dose-Hook Effect

Up to a tested concentration of 20 ng/ml testosterone, no High Dose Hook Effect was observed for the BioVendor Testosterone free in Saliva ELISA.

14. EXPECTED NORMAL VALUES

Because of differences, which may exist between laboratories and location with respect to population, laboratory technique and selection of reference group, it is important for each laboratory to determine its own normal and pathological values and to establish the appropriateness of adopting the reference range suggested here. Samples were collected in the morning.

	Men ♂			Women ♀		
Age Group Years	**5-95 Percentile (pg/ml)**	**Median pg/ml**	**n**	**5-95 Percentile (pg/ml)**	**Median pg/ml**	**n**
15 – 55	33.6-205.0	90.0	83	11.6-88.1	33.8	538
>55	25.1-140.7	68.3	42	9.3-83.0	27.2	137

	Children		
Age Group Years	**5th-95th Percentile (pg/ml)**	**Median pg/ml**	**n**
< 11	5.8-45.3	11.5	8

The results alone should not be the only reason for therapy. The results should be correlated to other clinical observations and diagnostic tests. Since testosterone levels show diurnal cycles, we recommend that the samples should be obtained at the same time each day.

15. PERFORMANCE CHARACTERISTICS

15.1 Analytical Sensitivity

The analytical sensitivity was calculated by subtracting 2 standard deviations (2SD) from the mean of at least twenty (20) replicate analyses of Calibrator 0. The analytical sensitivity of this assay is 6.1 pg/ml

15.2 Specificity (Cross Reactivity)

The following materials have been evaluated for cross reactivity. The percentage indicates cross reactivity at 50% displacement compared to Testosterone.

Steroid	% Cross reaction
5α-Dihydrotestosterone	23.3%
Androstenedione	32.2%
Androsteron	< 0.1%
5α-Androstane	< 0.1%
5ß-Androstane-3α,17ß-diole	< 0.1%
Corticosterone	< 0.1%
11-Desoxycorticosterone	< 0.1%
Dexamethasone	< 0.1%
Estradiol	< 0.1%
Progesterone	< 0.1%
17α-Hydroxyprogesterone	< 0.1%
Cortisol	< 0.1%
11-Desoxycortisol	< 0.1%
Cortison	< 0.1%
Estrone	< 0.1%
Pregnenolone	< 0.1%
Prednisone	< 0.1%
Prednisolon	< 0.1%
Estriol	< 0.1%
Danazol	< 0.1%

15.3 Assay dynamic range

The range of the assay is between 10 – 1000 pg/ml.

15.4 Reproducibility

15.4.1 Intra-Assay

The intra-assay variation was determined by 20 replicate measurements of three saliva samples within one run. The within-assay variability is shown below

	Sample 1	Sample 2	Sample 3
Mean (pg/ml)	388.2	41.5	137.3
SD	23.47	3.38	5.89
CV (%)	6.0	8.1	4.3
n =	20	20	20

15.4.2 Inter-Assay

The inter-assay (between-run) variation was determined by duplicate measurements of three saliva samples in ten different runs.

	Sample 1	Sample 2	Sample 3
Mean (pg/ml)	49.9	88.2	282.7
SD	4.24	6.05	21.38
CV (%)	8.5	6.9	7.6
n =	10	10	10

15.5 Recovery

Recovery was determined by adding increasing amounts of the analyte to three different samples containing different amounts of endogenous analyte. Each sample (non-spiked and spiked) was assayed. The percentage recoveries were determined by comparing expected and measured values of the samples.

Sample	Spiking (pg/ml)	Measured (pg/ml)	Expected (pg/ml)	Recovery (%)
1	native	50.7	-	-
	100	152.5	150.7	101%
	200	272.9	250.7	109%
	300	361.9	350.7	103%
2	native	15.0	-	-
	100	113.3	115.0	99%
	200	212.6	215.0	99%
	300	301.8	315.0	96%
3	native	82.7	-	-
	100	212.1	182.7	116%
	200	307.6	282.7	109%
	300	406.6	382.7	106%

15.6 Linearity

Three saliva samples containing different amounts of analyte were serially diluted with Calibrator 0 and assayed. The percentage linearity was calculated by comparing the expected and measured values.

Sample	Dilution	Measured (pg/ml)	Expected (pg/ml)	Linearity (%
1	native	288.5 150.6	-	-
	1 : 2	81.7	144.2	104%
	1 : 4	41.5	72.1	113%
	1 : 8		36.1	115%
2	native	125.2	-	-
	1 : 2	63.8	62.6	102%
	1 : 4	37.5	31.3	120%
	1 : 8	15.4	15.6	98%
3	native	80.7	-	-
	1 : 2	41.1	40.4	102%
	1 : 4	20.2	20.2	100%
	1 : 8	10.5	10.1	104%

16. LEGAL ASPECTS

16.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test.

The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact BIOVENDOR.

16.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 16.1. Any laboratory result is only a part of the total clinical picture of a patient.

Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived.

The test result itself should never be the sole determinant for deriving any therapeutic consequences.

16.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.

Claims submitted due to customer misinterpretation of laboratory results subject to point 16.2. are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

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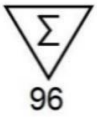
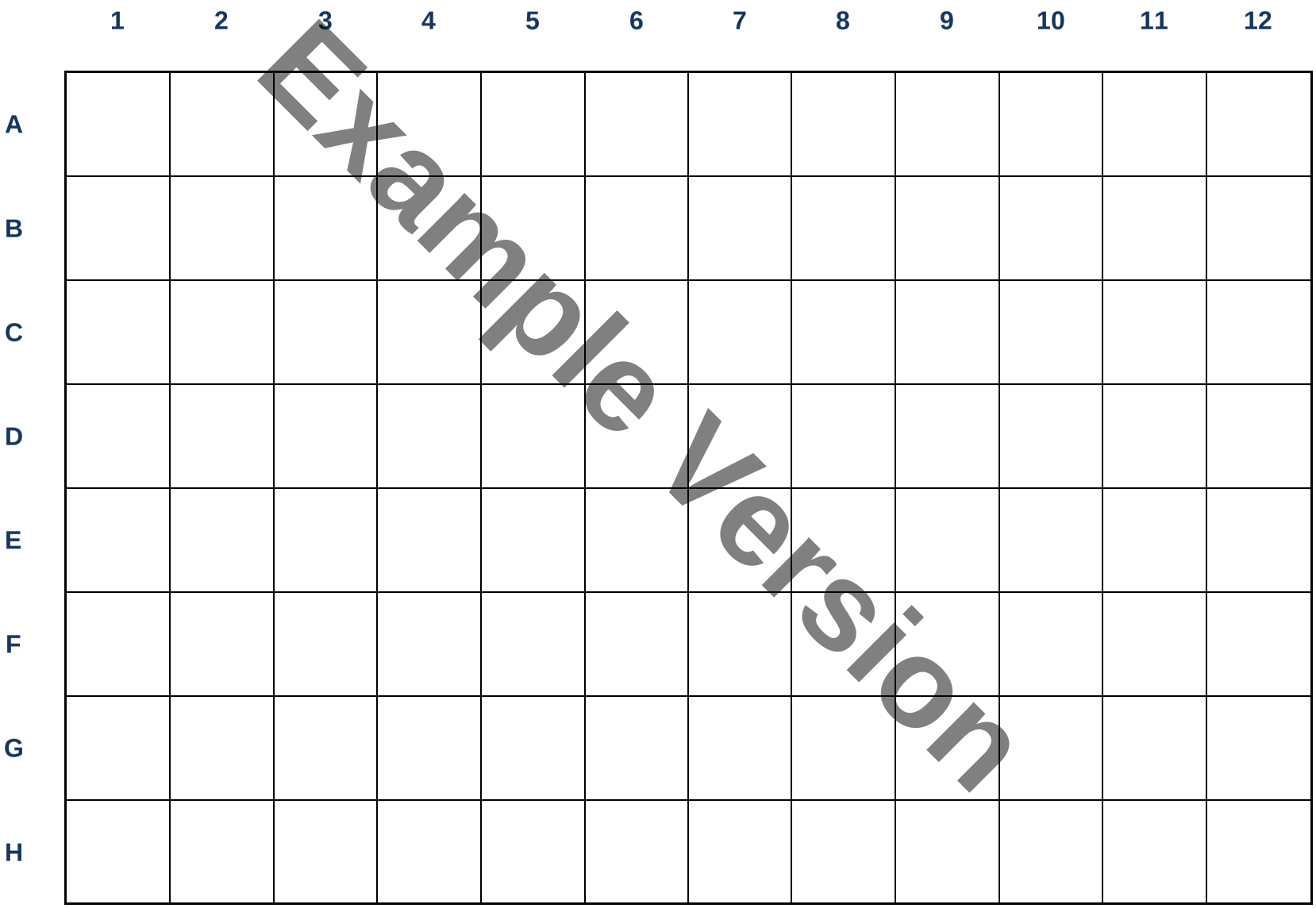
18. EXPLANATION OF SYMBOLS

REF	Catalogue number
LOT	Batch code
	Caution
	Use by date
	Temperature limit
	Manufacturer
	Read electronic instructions for use - eIFU
	The content is sufficient for 96 tests
	Biological risks



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