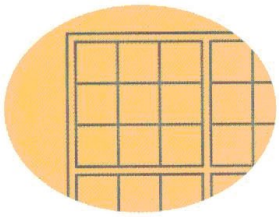
vetri plast®

IT. PAT. PEND.

Camere di conteggio
Counting chambers



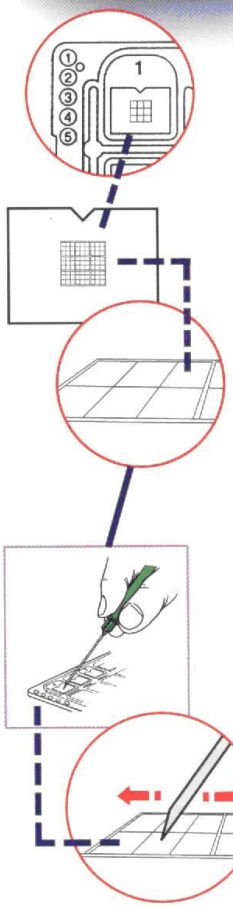
Vetrino con linee senza spessore

A causa dell'attuale sistema di costruzione degli stampi, le camere per liquidi biologici in plastica presentano sul piano di lettura una griglia di conteggio in rilievo.

Introducendo con un contagocce il liquido da esaminare attraverso il lato aperto delle camere, si investono i sistemi di conteggio in rilievo provocando turbolenze localizzate soprattutto in prossimità delle griglie.
Le particelle presenti negli strati inferiori del liquido in esame vengono fuorviate o escluse dal sistema di conteggio, costituito da linee che si elevano per circa il 10% dell'altezza totale della camera.

Vacutest con Vetriplast migliora il conteggio delle particelle, poichè la marcatura della griglia è ottenuta con un "sistema brevettato" di linee prive di spessore.

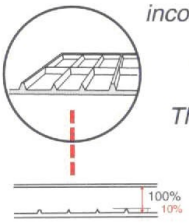
Il liquido da esaminare introdotto nelle camere di Vetriplast non incontra ostacoli nel regolare riempimento del pozzetto e della griglia e la distribuzione degli elementi figurati sul piano di lettura risulta omogenea.



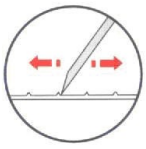
Slides with flat grid lines

Conventional plastic slides used to test urine and other biological fluids frequently incorporate raised counting grids to facilitate the measurement process.

These grid lines may rise from their base to as much as 10% of the entire height of the chamber.



Vetriplast, from Vacutest, provides a vast improvement over the conventional products since it utilizes a unique "patented system" of grid lines that are not raised at all but are flush with the base of the chamber.



The liquid specimen added to the Vetriplast chamber encounters no obstacles which can interfere with the testing since the distribution of the elements on the reading surface is perfectly homogeneous.

VACUTEST kima

VACUTEST KIMA srl Vacuum tubes - Via dell'Industria, 2 - 35020 Arzergrande (PD) Italy-Tel. +39 049.9720624 Fax +39 049.9720182 e-mail: info@vacutestkima.it

Code	***Description***
211710	**"VETRIPLAST"® plastic slide for urine sediment, 10 chambers, with counting grid**

Dimensions and specifications:

sides:	**83,0 mm side with 5 cells placement** **32,5 mm side with 2 cells placement**
slide total height:	**Max 1,74 mm**
colour:	**transparent**

Packing:

Single device	***Intermediate packing***	***External indivisible packing of sales***
None	**100 slides packaging (equal to 1.000 tests)** **Label provided with:** **REF – IVD – quantity – product description – lot – expiry date (year and month) – EC mark - manufacturer**	**1000 pcs boxes (equal to 10.000 tests)** **Label provided with:** **Manufacturer, EC, IVD, REF, quantity, description, production date, lot, expiry date, symbols of use and preservation, bar code**

Destination of use:

Cytologic urinary exam.

This product has to be used by professionally qualified personnel of analysis biomedical laboratories.

For instructions of use see following pages.

Composition material of the product:

POLYMETHYLMETHACRYLATE

(non-toxic material – transparent, particularly rigid with excellent optical qualities, water resistance and centrifugation resistance up to 1700G- given that it is the polymer that most resembles glass, in the medical field it is used particularly for test tubes for sierum)

Validity:

Shelf life of the device: 5 (five) years from manufacturing date

Storage and Conservation:

Storage and preservation for long periods must be at a temperature between + 5 and + 25°C, in a dry place

System applied during manufacturing and reference standards:

UNI EN ISO 9001:2015, ICIM certificate no 4264/5 issued by ICIM S.p.a. currently valid

UNI CEI EN ISO 13485:2016 ICIM certificate no 4265/5 issued by ICIM S.p.a., currently valid.

CE: quality guarantee system through issue of EC Declaration of Conformity after preparation of technical-productive files as per Directive EEC 98/79/EC available to the competent authorities

UNI CEI EN ISO 15223-1 symbols to be used on medical devices labels, labelling and information to be supplied

UNI EN 1041 Information to be supplied with the medical devices by the manufacturer

UNI EN 14971 – Application of risk management to medical devices.

Raw material certifications:

All raw materials used are non toxic, for certified food and medical uses, as per current European and FDA (USA) directives.

Disposal modality:

For the correct disposal please refer to the current national and local regulation concerning sanitary waste of the using country.

Disposal BEFORE use (for example: expired or deteriorated):

Classification: special waste comparable to municipal waste CER 15 01 02 or 20 01 39

Disposal AFTER use:

Classification: hazardous special waste CER 18 01 03* or 18 02 02*

Instructions for use for VETRIPLAST® slide

PREMISE:

In the VETRIPLAST slide (plastic slide with 10 cells) with counting grid, the microscopic counting of the elements present in the urine sediment, is based on the same principle of the glass counting chambers actually present on the market (Bürker, Thoma-Zeiss, Neubauer).

The above-mentioned counting chambers determine, through appropriate calculations, the number of the elements per ml, present in a sample of urine.

The surface on which the sample is spread in the chamber is divided in spaces defined by a grid.
Inside of the squares, the volume of the sample is predetermined and consequently, through calculation procedures, there is a direct connection between the number of cells counted on the squares and their amount in the quantity of the urine sample under examination.

The possibility of error in the cell counting of the urine sediment through the above-mentioned chambers could be the following:

Error depending on:

MATERIAL
a) non calibrated pipettes
b) defective counting chambers
c) cover glasses wrongly positioned or of bad quality

TECNIQUE
d) defective sampling
e) defective pipetting
f) defective mixing
g) samples drying

OPERATOR
h) differences between operators
i) operator with tired sight

VETRIPLAST differs from the traditional glass counting chambers for its easiness in the use; it helps the operator in the daily routine, decreases drastically some possible causes of error with the use of the chambers. VETRIPLAST increases the quality compared to the other plastic chambers thanks to the unique patented plastic grid. The total absence of thickness permits an homogeneous distribution on the counting grid of the elements present in the urine sample.

In the VETRIPLAST the volume of the sample limited by the grid is pre-determined and constant in all the cells (every slide is subject to strict quality controls during the production).

The area delimited by the grid is 3mm by 3mm divided in 9 squares with a side of 1 mm, defined by a double line. Every square of 1mm side is also divided in 9 small squares with a side of 0,333mm, defined by a single line.
Every grid is divided in 81 small squares with a side of 0,333mm.

In this way a precise subdivision of the sample value on the grid is obtained.
0,9 ul on the whole counting grid

0,1 ul inside of each of the 9 squares of 1x1mm side
0,0111ul inside of each of the 9 small squares of 0,333 x 0,333mm side

Features of VETRIPLAST slide:

1) reduces the number of glass slides to be prepared;
2) avoids the use of defective counting chambers;
3) no need to put a cover glass avoiding every error;
4) ensures the precision of the sample volume inside every chamber and every grid;
5) permits a quick examination of the sample, avoiding the possibility of drying;
6) reduces the possibility of overcrowding of the cells.

DIRECTIONS

For 10 ml of centrifuged urines:

After having sufficiently inverted the sample of urine, pour 10 ml into a conical test tube;

⇒ centrifuge for 5 minutes at 1000-1500 rpm.

⇒ Pour off 9 ml of the top fluid;

⇒ Suspend the sediment again, sufficiently inverting the test tube;

⇒ Remove the suspension with a Pasteur capillary pipette and fill the selected cell on the slide.

⇒ Identify the grid position at 100 magnifications and then read at 400 magnification. The field of reading will include the smallest square of the grid (0,333 x 0,333mm side).

For not centrifuged urines:

After having adequately inverted the urine sample:

⇒ Collect the suspension with a Pasteur capillary pipette and fill the selected cell of the slide.

⇒ Identify the grid position at 100 magnifications and then read at 400 magnification. The field of reading will include the smallest square of the grid (0,333 x 0,333mm side).

READING AND COUNTING THE CELLS IN THE GRID

Indipendently from the counting directions given, there could be a percentage of error due to the random distribution of the elements in the chamber.

The error percentage could be reduced by counting a bigger number of elements in the squares.
It is therefore necessary that the operator establishes the way of counting depending on the number of elements in the sample under examination.

FORMULA FOR THE COUNTING OF THE ELEMENTS IN URINES

$$\frac{n}{k * N * F} = \mathbf{T_{\mu}}$$ to obtain values expressed in number of elements per **µl** of urine

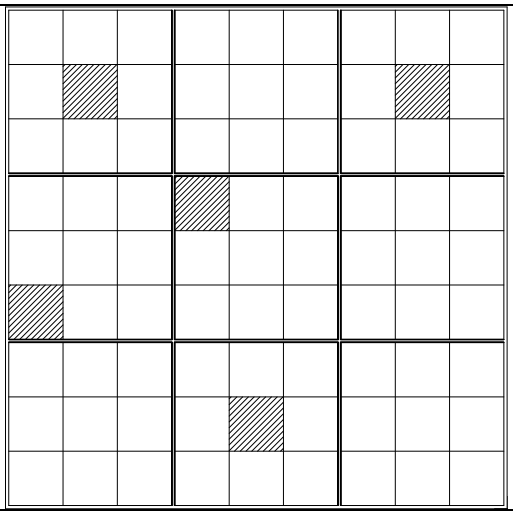
OR

$$\frac{n * 1000}{k * N * F} = \mathbf{T_{ml}}$$ to obtain values expressed in number of elements per **ml** of urine

where:

n = total number of counted elements
k= 0,01111
N= number of examined cells
F= preservation factor (10 or 1)
T_{μ} = total elements present in 1µl of urine
T_{ml} = total elements present in 1 ml of urine

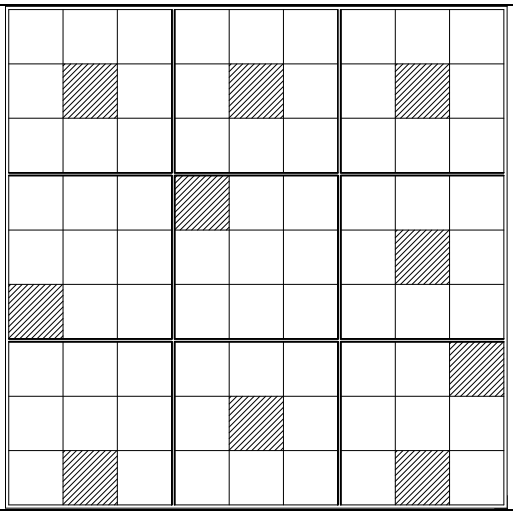
EXAMPLES OF READING AND TABLES FOR QUICK CALCULATION

High number of elements	**Picture no 1**
To count the number of elements present in 5 different cells by giving particular attention not to read twice in the same point. An example of possible reading is shown in **picture no 1** on the right.	

The total number of elements per **ml** of urine can be obtained by using **table 1** here below.

Table no 1

Total number of elements counted in **5** cells	Number of elements present in 1 **ul** of concentrated urine **1:10**	Number of elements present in 1 **ul** of **whole** urine	Number of elements present in 1 **ml** of concentrated urine **1:10**	No. Of elements present in 1 **ml** of **whole** urine	Total number of elements counted in **5** cells	Number of elements present in 1 **ul** of concentrated urine **1:10**	No. Of elements present in 1 **ul** of **whole** urine	Number of elements present in 1 **ml** of concentrated urine **1:10**	No. Of elements present in 1 **ml** of **whole** urine
1	2	18	1800	18000	**35**	63	630	63000	6300000
2	4	36	3600	36000	**40**	72	720	72000	7200000
3	5	54	5400	54000	**45**	81	810	81000	8100000
4	7	72	7200	72000	**50**	90	900	90000	9000000
5	9	90	9000	90000	**55**	99	990	99000	9900000
6	11	108	10800	108000	**60**	108	1080	108000	1080000
7	13	126	12600	126000	**65**	117	1170	117000	1170000
8	14	144	14400	144000	**70**	126	1260	126000	1260000
9	16	162	16200	162000	**75**	135	1350	135000	1350000
10	18	180	18000	180000	**80**	144	1440	144000	1440000
12	22	216	21600	216000	**85**	153	1530	153000	1530000
14	25	252	25200	252000	**90**	162	1620	162000	1620000
18	32	324	32400	324000	**95**	171	1710	171000	1710000
20	36	360	36000	360000	**100**	180	1800	180000	1800000
25	45	450	45000	450000	**105**	189	1890	189000	1890000
30	54	540	54000	540000	**110**	198	1980	198000	1980000

Low number of elements	**Picture 2**
To count the number of elements present in 10 different cells by giving particular attention not to read twice in the same point. An example of possible reading is shown in **picture no 2** on the right.	

The total number of elements present per ul or ml of urine can be obtained by using **table 2** here below.

Table no.2

Total number of counted elements in **10** cells	No. Of elements present in 1 **ul** of concentrated urine **1:10**	No. Of elements present in 1 **ul** of **whole** urine	No. Of elements present in 1 **ml** of concentrated urine **1:10**	No. Of elements present in 1 **ml** of **whole** urine	Total number of counted elements in **10** cells	No. Of elements present in 1 **ul** of concentrated urine **1:10**	No. Of elements present in 1 **ul** of **whole** urine	No. Of elements present in 1 **ml** of concentrated urine **1:10**	No. Of elements present in 1 **ml** of **whole** urine
1	1	9	900	9000	**35**	31	320	31500	315000
2	2	18	1800	18000	**40**	36	360	36000	360000
3	3	27	2700	27000	**45**	40	405	40500	405000
4	4	36	3600	36000	**50**	45	450	45000	450000
5	5	45	4500	45000	**55**	50	500	49500	495000
6	5	54	5400	54000	**60**	54	540	54000	540000
7	6	63	6300	63000	**65**	59	590	58500	585000
8	7	72	7200	72000	**70**	63	630	63000	630000
9	8	81	8100	81000	**75**	68	680	67500	675000
10	9	90	9000	90000	**80**	72	720	72000	720000
12	11	108	10800	108000	**85**	77	770	76500	765000
14	13	126	12600	126000	**90**	81	810	81000	810000
18	16	162	16200	162000	**95**	86	860	85500	855000
20	18	180	18000	180000	**100**	90	900	90000	900000
25	23	225	22500	225000	**105**	95	950	94500	945000
30	27	270	27000	270000	**110**	99	990	99000	990000