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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

**CERTIFICATO N.
CERTIFICATE N. 9124.BSGM**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

BIOSIGMA SPA

VIA VALLETTA 6 FRAZ. Z.I. CANTARANA - 30010 CONA (VE)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA VALLETTA 6 FRAZ. Z.I. CANTARANA - 30010 CONA (VE)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione e immissione in commercio di articoli monouso da laboratorio e diagnostici in vitro sterili e non sterili. Commercializzazione e distribuzione di dispositivi medici (non attivi, sterili o non sterili, non impiantabili) diagnostici in vitro (sterili e non sterili), articoli da laboratorio, vetreria, accessori per strutture sanitarie pubbliche e private

Design, production and placement on the market of disposable labware items and in vitro diagnostics sterile or non sterile. Trading and distribution of medical devices (non-active, sterile and not sterile and non-implantable), in vitro diagnostics labware items (sterile and non sterile), glassware and accessories for public and private healthcare facilities

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION 2013-10-04	EMISSIONE CORRENTE CURRENT ISSUE 2022-09-23	SCADENZA EXPIRY 2025-10-03
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



DICHIARAZIONE DI CONFORMITÀ UE / EU DECLARATION OF CONFORMITY

Fabbricante:
Manufacturer:

BIOSIGMA S.p.A.
Via Valletta, 6
30010 - Cantarana di Cona (VE) - ITALY
Tel. +39.0426.302224 - Fax +39.0426.302228
E-mail: info@biosigmaeu.com
<http://www.biosigma.com> - <http://www.biosigma.it>

SRN Numero di Registrazione Unico:
SRN Single Registration Number:

IT-MF-000030370

Dichiara sotto la propria responsabilità che i dispositivi medico-diagnostici in vitro:
Declare under its own responsibility that in vitro diagnostic medical devices:

VETRINI PER SEDIMENTO URINARIO
URINARY SEDIMENT SLIDES
Vedi elenco codici allegato
See the enclosed codes list

UDI-DI di Base: 803367356FASTREAD102V4
Basic UDI-DI:

Destinazione d'uso / Intended purpose

Dispositivi monouso destinati all'uso in laboratorio per la lettura standardizzata del sedimento urinario tramite microscopio ottico.
Disposable devices intended for use in the laboratory for the standardized reading of urinary sediment using an optical microscope.

Classificazione secondo il REGOLAMENTO (EU) 2017/746, Allegato VIII.
Classification according to REGULATION (EU) 2017/746, Annex VIII.

Classe A / Class A **Sterile / Sterile**
 Classe B / Class B
 Classe C / Class C
 Classe D / Class D

Sono conformi al REGOLAMENTO (UE) 2017/746 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 5 aprile 2017 e, se del caso, a qualunque altro pertinente atto legislativo dell'Unione che preveda il rilascio di una dichiarazione di conformità UE;

Are manufactured in compliance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Organismo Notificato incaricato della valutazione della conformità (se consultato):
Notified Body (if consulted):

Nome: Non Applicabile / *Not Applicable*

N° identificativo/Identification No.

Certificato N°/ Registration No.

Cantarana di Cona (VE), 07/11/2022
Luogo, data / Place, date

Nome e funzione / Name and function
MARCOLIN MARTINO
Legale Rappresentante / Legal Representative



Biosigma S.p.A.

a dominique Dutscher Company

Via Valletta, 6 | 30010 Cantarana di Cona (VE), Italy | Tel. ++39 0426 302224 | Fax ++39 0426 302228 |
Email info@biosigmaeu.com | www.biosigma.it | www.biosigma.com | Cap. Soc. 99.000 € i.v. | C.F. 02173800281 |
Codice SDI: MZO2A0U | P.IVA IT 03328440270 | N. 298577 R.E.A. di Venezia | Registro A.E.E. IT0903000005843 | R.N.P.P.A. IT11080P00002626



DICHIARAZIONE DI CONFORMITÀ UE / EU DECLARATION OF CONFORMITY

ELENCO CODICI / CODES LIST

REF	DESCRIZIONE	DESCRIPTION
BVS100	Fast-Read 102	<i>Fast-Read 102</i>
BVS100H	Fast-Read 102	<i>Fast-Read 102</i>
U9027	URIGLASS	<i>URIGLASS</i>
04163419001	Fast-Read 102	<i>Fast-Read 102</i>
4242	Fast-Read 102	<i>Fast-Read 102</i>



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Email info@biosigmaeu.com | www.biosigma.it www.biosigma.com | Cap. Soc. 99.000 € i.v. | C.F. 02173800281 |
Codice SDI: MZ02A0U | P.IVA IT 03328440270 | N. 298577 R.E.A. di Venezia | Registro A.E.E. IT0903000005843 | R.N.P.P.A.
IT11080P00002626



Biosigma

Fast-Read Rev. 2021_01

Made in Italy

Fast Read 102[®] Disposabile slide for cell counting

Biosigma S.p.A. a dominique Dutscher Company
Via Valletta, 6 - 30010 Cona (Venice) • Italy
Tel. ++39 0426 302226 • Fax ++39 0426 302228
Email: export@biosigmaeu.com
WEB: www.biosigma.com



ISO 13485



ISO 14001



UNI ISO 45001:2018

FOR THE STANDARDIZATION OF MICROSCOPIC URINALYSIS

FAST READ 102[®] system improves the standardization of microscopic urinalysis and provides precision and reproducibility such as to guarantee constant readings which will not be influenced by variations of techniques among different operators.

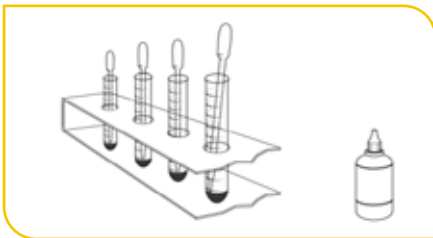
FAST READ 102[®] is made of a slide, protected by an optically transparent film, with 10 independent chambers containing a standard volume of 7 μ L. After dispensing the sample on the slide application area by means of a capillary mechanism, the sediment is homogeneously distributed in the reading chamber. Each chamber is fitted with its own system for the collection of excess urine to prevent any possible contamination.

Furthermore FAST READ 102[®] slide allows easy identification of the sample by using the numbers printed on the sides.

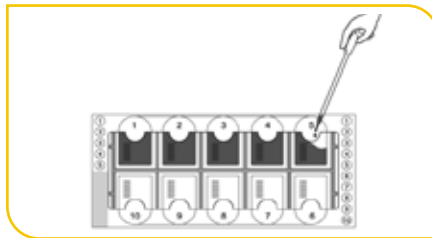


MATERIALS: The device BVS100 is manufactured in METHACRYLATE: rigid, transparent, resistant to atmospheric agents, it replace the glass in every its application in which it reach high temperature (lower than 90-100 °C).

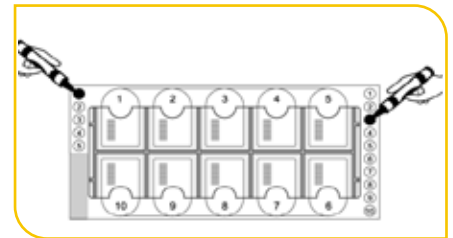
CE This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices



After completing the preparation of the urinary sediment by normal centrifugation, insert a pipette into the test tube and dispense one drop of STAIN.



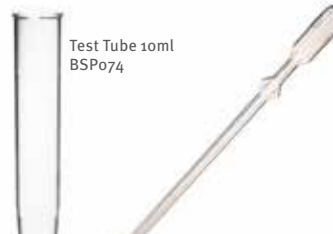
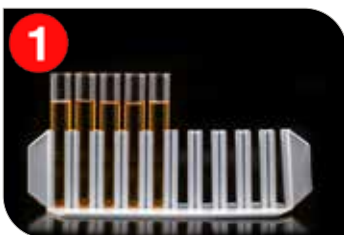
Use the pipette to mix the urinary sediment by repeatedly pressing the bulb; then dispense a drop of sample onto the appropriate area of the slide.



HOW TO USE THE NUMBERING SYSTEM
Example: For the identification of samples from number 131 to 140 mark number 1 on the left side and number 3 on the right side of the slide.

M-T system

M-T microtips[®] is a Biosigma's registered trade marks



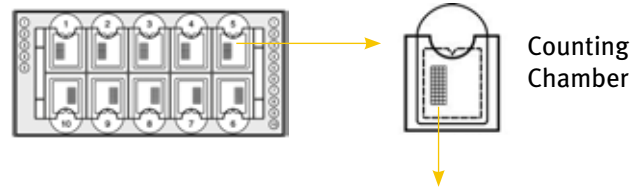
It's very important matter during urine sedimentation count, that operators always use the same sample preparation method in order to have tests' repeatability. Furthermore, with traditional urine reading system actually in use in many laboratories, sedimentation compaction creates a superimposition of epithelial cells. That cause difficulties in verifying the presence amount of different cells components. With Biosigma M-T System it is possible to overcome this inconveniences in a few standardisation steps during sample preparation.

1. Fill BSP074 tests tubes with 10ml of urine and then centrifuge.
2. Insert tribulb M-T Microtips[®] BSV143 making sure to trap the tubes.
3. Overturn the rack to come out the excess urine.
4. You get 1 ml of sediment, resuspended, is ready to be analysed on Fast Read 102[®] Slides.
5. Deposit a drop in the Fast Read 102[®] cell.

CALCULATION METHOD FOR CELLS / μL IN URINARY SEDIMENT

FAST READ 102[®] is a disposable plastic device composed of 10 counting chambers. With each device you can analyze 10 samples.

Each room contains a GRID composed of 10 SQUARES, each of which is divided into 16 smaller squares (called SECTORS). One of the advantages of employing FAST-READ is the ease in determining the cells per μL in the specimen.



1. Perform the count on a centrifuged fresh urine sample, after having decanted.
2. Gently resuspend the sediment.
3. Using a pipette, introduce the sample into the well and examine under the microscope the area of the grid
4. Count the number of cellular elements within N squares

$$\text{Cell. / } \mu\text{l} = \frac{(\sum \text{ cells counted in square N}) \times \text{concentration factor} \times 10}{N}$$

Concentration factor = Volume of sediment / Volume centrifuged urine
10: conversion from 0,1 μl to 1 μl

For uncentrifuged urine, don't to multiply the number of cells counted for the concentration factor.

METHOD OF CELL COUNTS FOR DILUTED SAMPLES (CELLS / ML)

After filling the counting chamber with the sample, proceed to the counting of cells distributed in N squares.

Considering that the grid consists of 10 squares, each square has a dimension of 1 x 1 mm, a depth of 0.1 mm and a volume of 0.1 μl , the formula for determining the concentration of cells (cells / ml) is:

$$\text{Cells / ml} = \frac{(\sum \text{ cells counted in square N}) \times \text{dilution factor} \times 10^4}{N}$$

10⁴ = conversion 0,1 μl in 1 ml

Attention to the cells on the edges, you should only count those on either side, to avoid the risk of over or under.

In the example shown we perform the cell count of a sample diluted 100 times:

N = 5 (number of squares considered for counting)

Σ cells counted in 5 square = 67

Dilution factor = 10²

$$[\text{Cells / ml}] = (67/5) \times 10^2 \times 10^4 = 13.4 \times 10^6$$

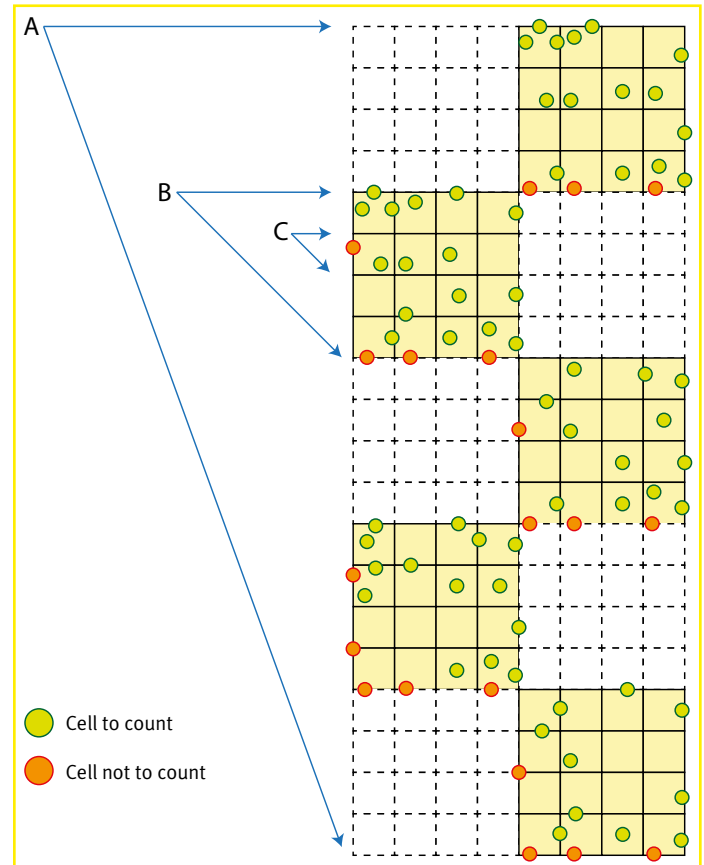
Publication in scientific journal.

Validation of analytical methods in GMP: the disposable Fast Read 102[®] device, an alternative practical approach for cell counting.

Gunetti M, Castiglia S, Rustichelli D, Mareschi K, Sanavio F, Muraro M, Signorino E, Castello L, Ferrero I, Fagioli F.

J. Transl Med. 2012 May 31;10:112

www.Translational-medicine.com/content/10/1/112



A: GRID

Dimensions	2 mm x 5 mm
Depth	0,1 mm
Volume	1 μl
Each grid includes	10 squares
Cell volume	7 μl

B: SQUARE








Dimensions	1 mm x 1 mm
Depth	0,1 mm
Volume	0,1 μl
Each square includes	16 sector

C: SECTOR

Dimensions	0,25 mm x 0,25 mm
Depth	0,1 mm
Volume of sector	0,00625 μl

KIT FAST-READ® How to Order

1 kit = 1.000 determinations

	Fast-Read® 102	M-T Microtips®	Pasteur Pipettes in PE	Test Tube 10 ml in PS	White Cap aside	Test Tube 10 ml in PS labelled with white cap	Stain urinary sediment
	(BVS100)	(BSV143)	(BSV140)	(BSP074)	(BSO026)	(BSP112)	(BSV135)
REF.							
BVS100	○						
BVS101	○		○				
BVS102	○		○				○
BVS190		○		○			
BVS171	○	○					
BVS1715	○	○		○			
BVS1719	○	○		○	○		
BVS1717	○	○		○			○
BVS1720	○	○		○	○		○
BVS1721	○	○				○	○

Urinalysis controls validate performance for consistency and accuracy

KOVA® Urinalysis Controls Validate Performance for Consistency and Accuracy

For quality control, use KOVA controls to validate the performance of urine chemistry test strips and readers and to help focus microscopic sediment analysis. KOVA Liqua-Trol™ is a ready-to-use bi-level liquid control for use with all major brands of urine chemistry dipsticks.

KOVA® Liqua-Trol™

Ready-to-use liquid control.

External quality control of physical, chemical and microscopic examination of urine specimens. Available with or without microscopic.

Two levels of controls to monitor complete decision range for urine strip chemistries.

Value assignments available on all major systems for visual and instrument analysis.

Stability: 30 days at room temperature and up to 27 months shelf life for the full labeled dating when stored in a refrigerator (2-8°C).



Individual and Combination Packs

CAT. NO.	Description	Bottle (ml)	Sale unit
87112E	KOVA Liqua-Trol Level I (Abnormal) and Level II (Normal w/ hCG); bi-level 3x15mL	15	6
87122E	KOVA Liqua-Trol Level II (Normal) with hCG and microscopics	120	2
87176E	KOVA Liqua-Trol Level I (Abnormal) with microscopics	120	2
87123E	KOVA Liqua-Trol Level II (Normal) with hCG and microscopics	120	4
87177E	KOVA Liqua-Trol Level I (Abnormal) with microscopics	120	4