

	URINE 2026 - JANUARY 2026	RdP: Final Revision ZMD001_15_2026_1_1.pdf	
	Participant : ZMD001 Sample Lot : UR-2601	Issued on 11/02/2026 Authorized by RQS Sonia Zanghini	

Bio-Group Medical System s.r.l.

QS Division

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Cycle: URINE 2026; JANUARY 2026

Enroled participants : 193

Subcontract Activities: Homogeneity and stability test and sera production. The PTP declares the assumption of responsibility towards the participants for the subcontracted work

Authorized by: RQS Sonia Zanghini

Coordinator: COP Luigi Polidoro

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Proficiency test object: Urine

Lot: UR-2601

Lot expiration: 2026-05-31

Homogeneity: Data available on request

Confidentiality: All communications relating to the QS programs take place in a confidential manner between the QS Division and each individual laboratory. Participants are assigned a specific confidential identification code. These reserved codes are known to the QS Division, to the single laboratory and to the appointed officers.



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Analyte	RDS
UROBILINOGEN	0,1500
KETONES	0,1500
BLOOD	0,1500
PROTEIN	0,1500
PH	0,1500
GLUCOSE	0,1500
MICROALBUMIN	0,1500
SPECIFIC GRAVITY	0,1500
NITRITE	0,1500
ASCORBIC ACID	0,1500
BILIRUBIN	0,1500
LEUKOCYTES	0,1500
ALBUMINA U	0,0000

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PT target value assignment procedure

For each measurement of this evaluation test, the assigned value is determined using the robust average calculated according to Algorithm A ISO 13528:2015.
 Standard uncertainty is determined according to formula:

$$U_{x_{pt}} = 1,25 \left(\frac{s^*}{\sqrt{p}} \right)$$

where s^* is the robust standard deviation and p is participants number

Assigned Relative Deviation Standard is determined according to reported formula: where RDS is relative standard deviation calculated on the historical basis

$$\sigma_{pt} = RDS * x_{pt}$$

Performance index is evaluated according to equation B.3 ISO 17043:2023

$$Z \text{ Score} = \frac{x_i - x_{pt}}{\sigma_{pt}}$$

If standard uncertainty is more than 30% of Assigned Relative Deviation Standard the performance index will be determined according to the following equation

$$\frac{x_i - x_{pt}}{\sqrt{\sigma_{pt}^2 + U_{x_{pt}}^2}}$$

Where:

x_i = Participant measure

x_{pt} = Assigned value

σ_{pt} = Assigned standard deviation

$U_{x_{pt}}$ = Standard uncertainty

The exposed procedure is used for all the parameters of this PT

In this report are shown also these two error indexes

$D = x_i - x_{pt}$: Participant absolute error

$D_{\%} = \frac{(100 * D)}{x_{pt}}$: Absolute error in percentage

Target value assignment procedure

For each measurand of this evaluation test the assigned value is determined by reporting the result expressed by the highest number of participants in percentage

Performance index

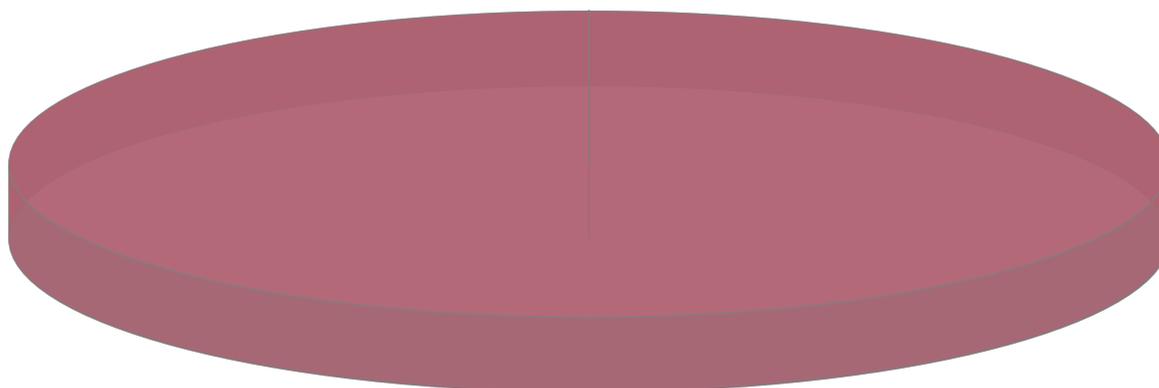
""If the result provided matches the assigned value, the ""Acceptable"" judgment will be given as a performance index. If the result provided does not correspond to the assigned value, the judgment will be provided, as a performance index: ""unacceptable""

Analyte **NITRITE**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

responses distribution



● NEGATIVE ● DOUBT ● POSITIVE

Participants number	14		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

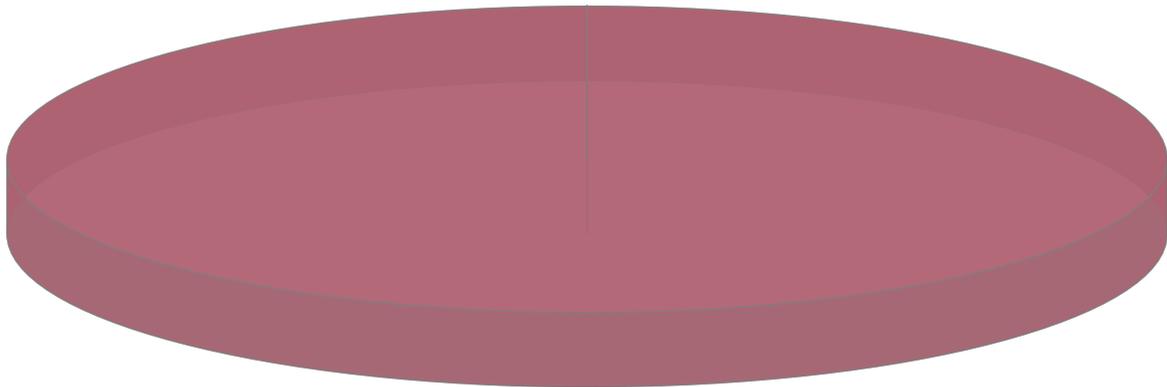
FEBRUARY 2026
ACCEPTABLE

Analyte **BLOOD**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

responses distribution



● NEGATIVE ● DOUBT ● POSITIVE

Participants number	31		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

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Analyte **SPECIFIC GRAVITY**

Unit of measure elaborated **ratio**

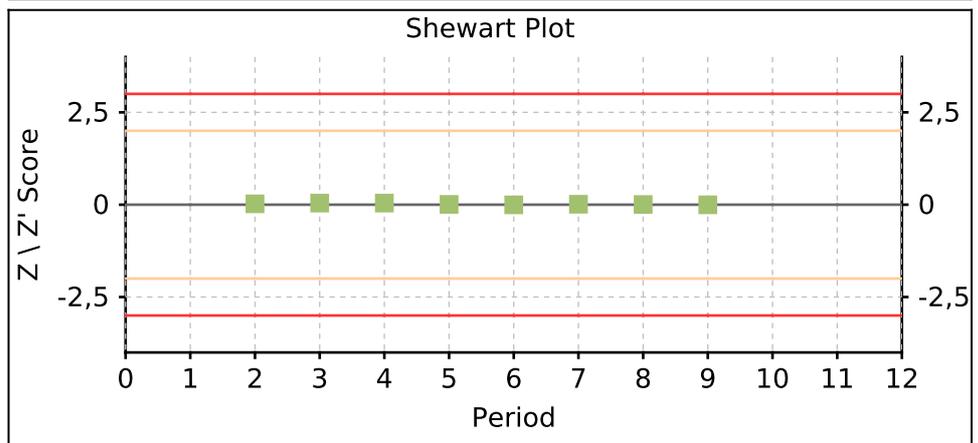
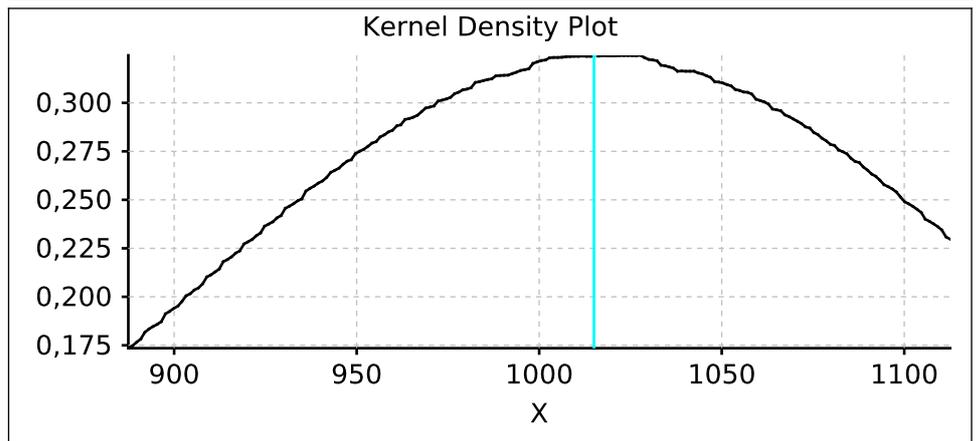
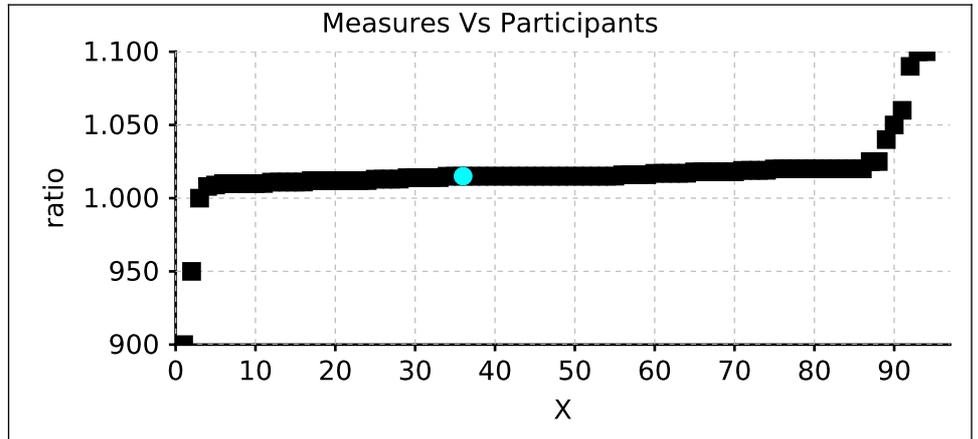
RDS **0,1500**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

Participants number **95**

Measure	1015,00
Z Score	-0,00
Standard Deviation	4,19
Consensus Value	1015,48
Assigned DS	152,32
Standard Uncertainty	0,54
CV	0,41
Difference	-0,48
D%	-0,05



100.00% of last 8 ZScore is in standard deviation range -2 +2



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Analyte **UROBILINOGEN**

Unit of measure elaborated **mg/dL**

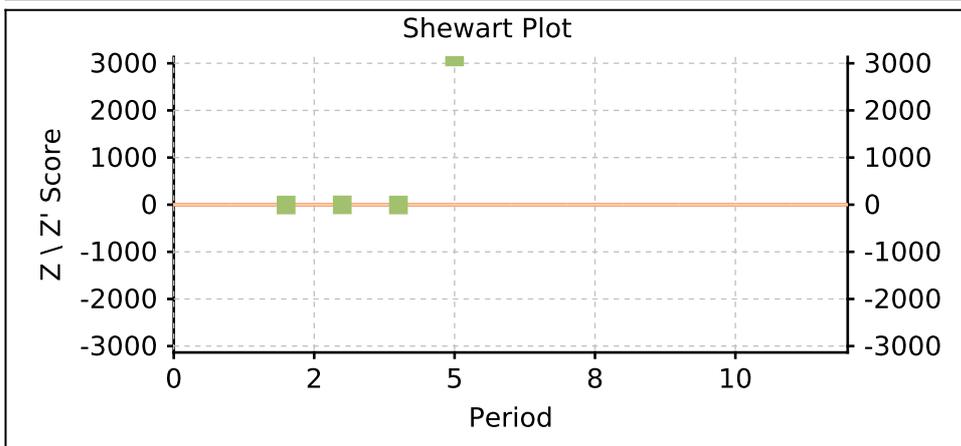
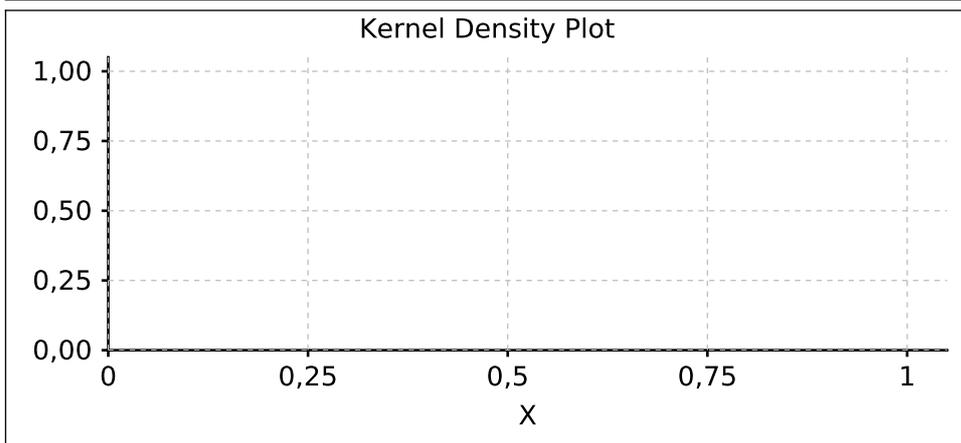
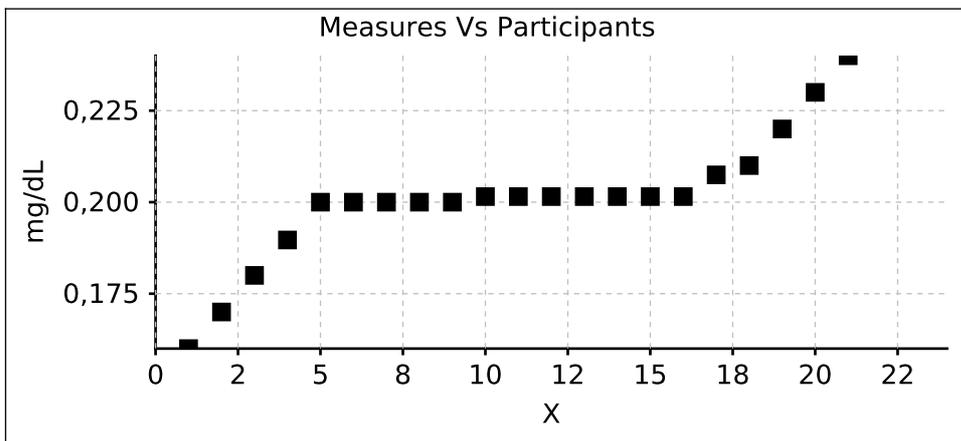
RDS **0,1500**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

Participants number **25**

Measure	94,84
Z Score	3133,60
Standard Deviation	0,00
Consensus Value	0,20
Assigned DS	0,03
Standard Uncertainty	0,00
CV	0,00
Difference	94,63
D%	47011,85



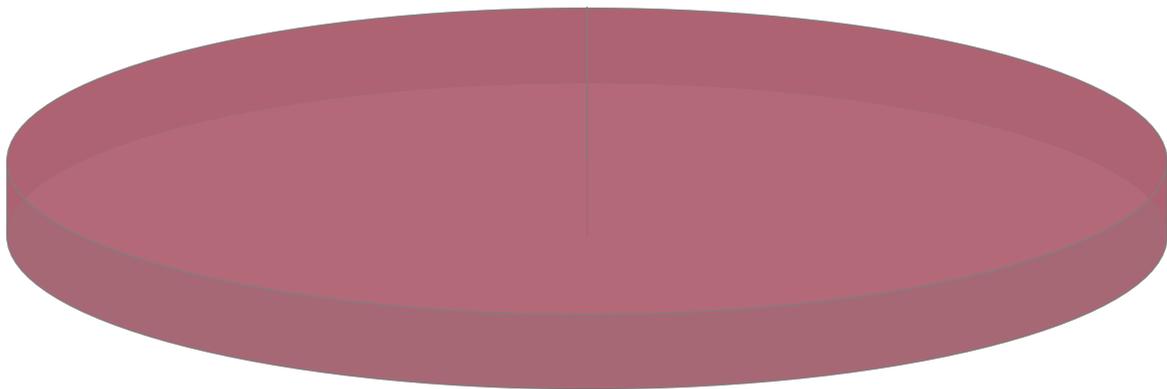
0.00% of last 4 ZScore is in standard deviation range -2 +2

Analyte **GLUCOSE**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

responses distribution



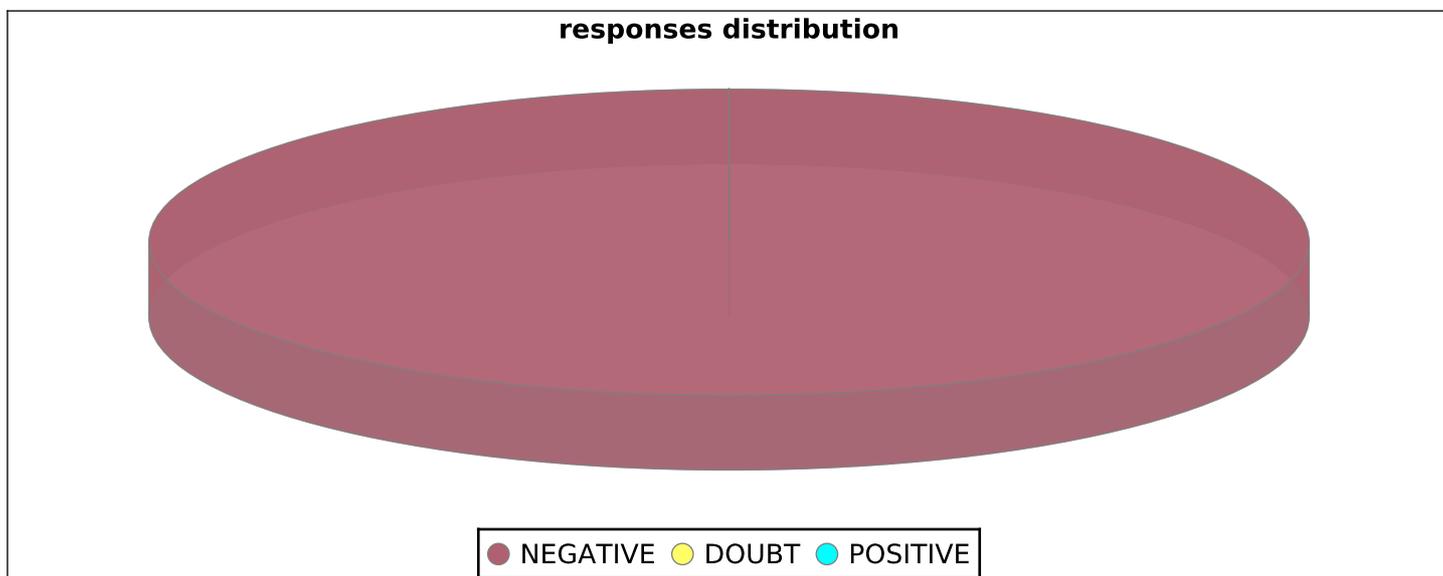
● NEGATIVE ● DOUBT ● POSITIVE

Participants number	20		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

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Analyte **ASCORBIC ACID** Analyzer **Manual - Manual** Method **Dry Chemistry**



Participants number	23		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

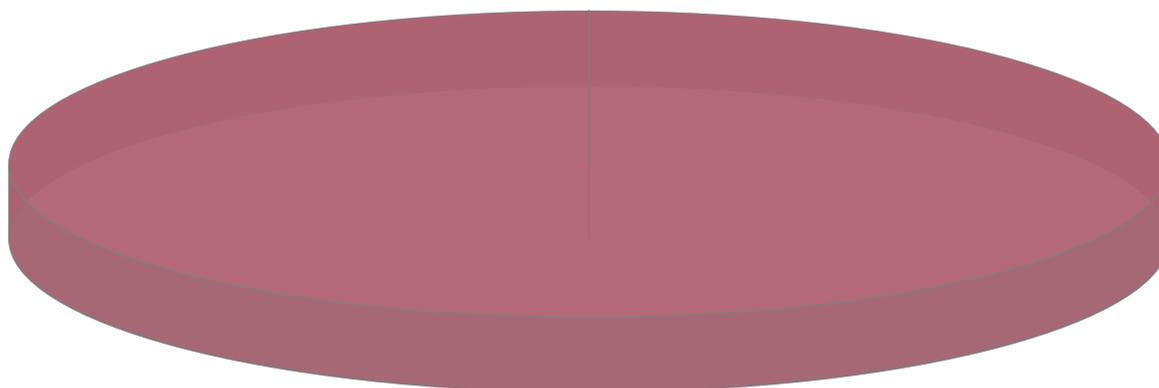
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ACCEPTABLE

Analyte **KETONES**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

responses distribution



● NEGATIVE ● DOUBT ● POSITIVE

Participants number	29		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

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Analyte **PH**

Unit of measure elaborated **ratio**

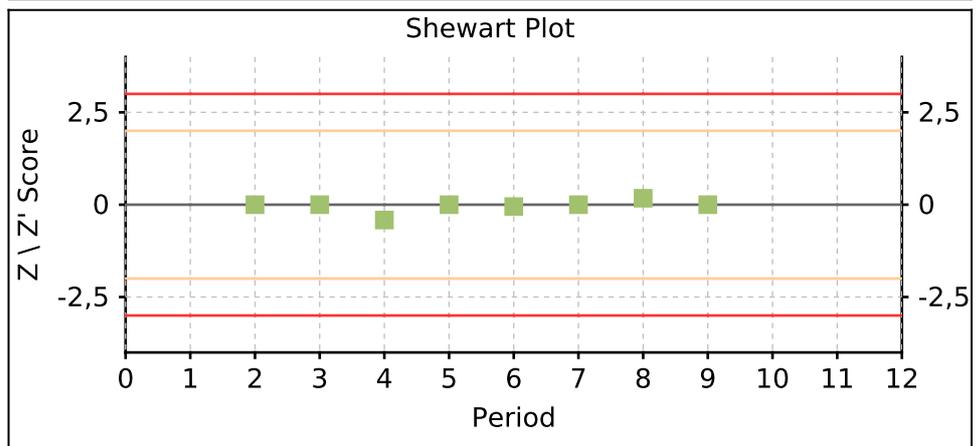
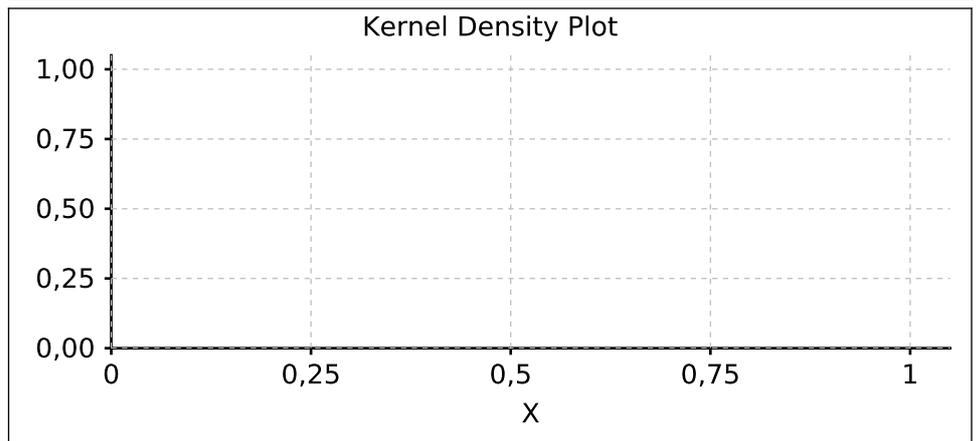
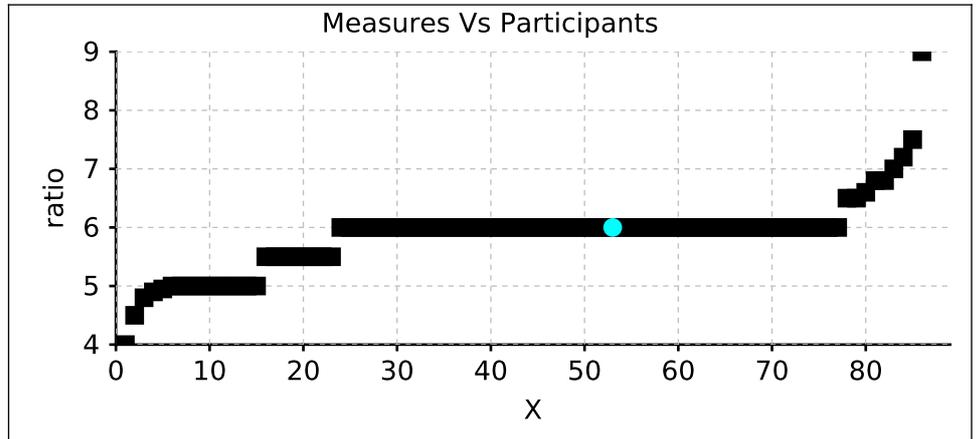
RDS **0,1500**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

Participants number **87**

Measure	6,00
Z Score	0,00
Standard Deviation	0,00
Consensus Value	6,00
Assigned DS	0,90
Standard Uncertainty	0,00
CV	0,00
Difference	0,00
D%	0,00



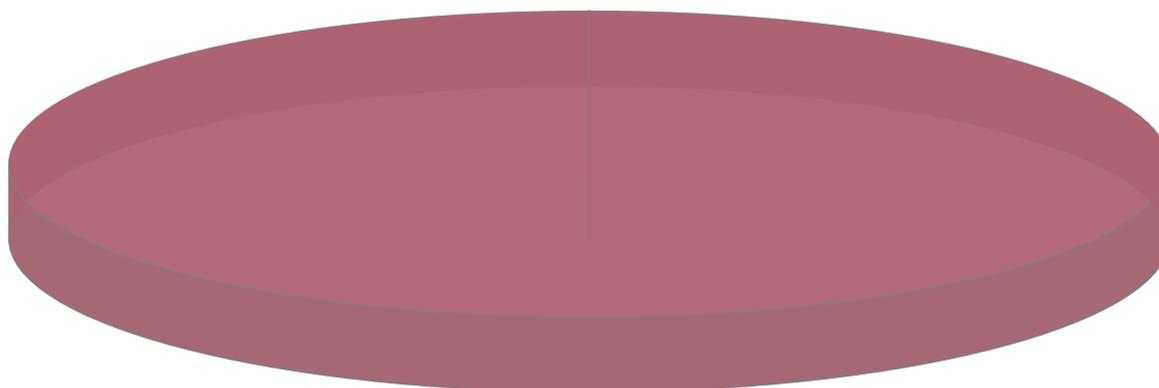
100.00% of last 8 ZScore is in standard deviation range -2 +2

Analyte **BILIRUBIN**

Analyzer **Manual - Manual**

Method **Dry Chemistry**

responses distribution



● NEGATIVE ● DOUBT ● POSITIVE

Participants number	21		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

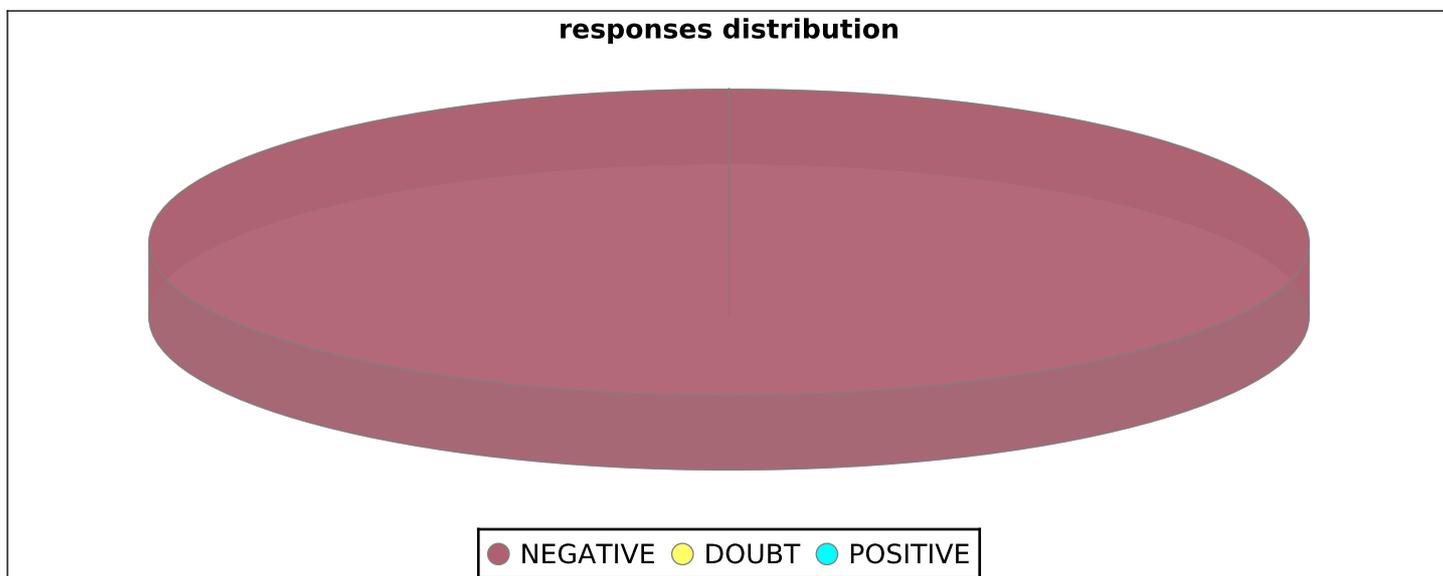
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Analyte **LEUKOCYTES**

Analyzer **Manual - Manual**

Method **Dry Chemistry**



Participants number	12		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

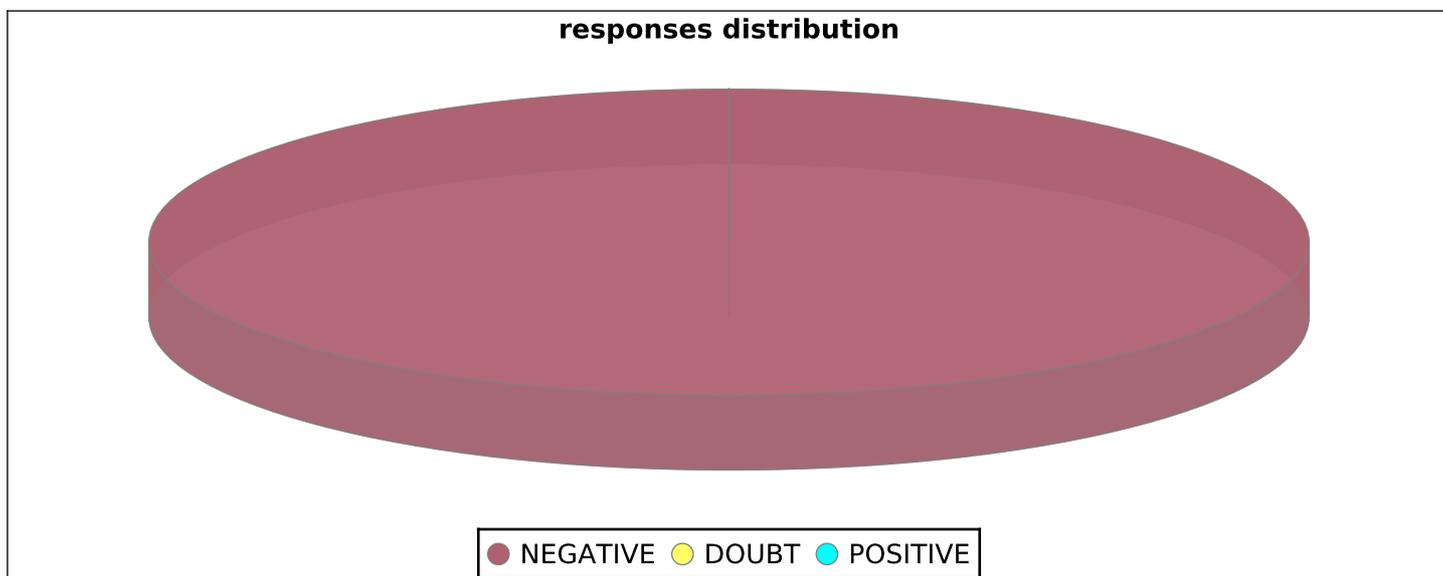
FEBRUARY 2026
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Analyte **PROTEIN**

Analyzer **Manual - Manual**

Method **Dry Chemistry**



Participants number	12		
NEGATIVE	100,00 %	Measure	NEGATIVE
POSITIVE	0,00 %	lbl_risultato_atteso	NEGATIVE
DOUBT	0,00 %	performance index	ACCEPTABLE

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Analyte	Consensus Value	Measure	Standard Deviation	CV	Z \ Z'	Z Score	D%	REMARK
SPECIFIC GRAVITY	1015,4 ratio	1015,0 ratio	4,19	0,41	Z	-0,00	-0,05	OK
UROBILINOGEN	0,20 mg/dL	1,60 mmol/L	0,00	0,00	Z	3133,6	47011,85	ACTION
PH	6,00 ratio	6,00 ratio	0,00	0,00	Z	0,00	0,00	OK

Analyte	Measure	lbl_risultato_atteso	performance index
NITRITE	NEGATIVE	NEGATIVE	ACCEPTABLE
BLOOD	NEGATIVE	NEGATIVE	ACCEPTABLE
GLUCOSE	NEGATIVE	NEGATIVE	ACCEPTABLE
ASCORBIC ACID	NEGATIVE	NEGATIVE	ACCEPTABLE
KETONES	NEGATIVE	NEGATIVE	ACCEPTABLE
BILIRUBIN	NEGATIVE	NEGATIVE	ACCEPTABLE
LEUKOCYTES	NEGATIVE	NEGATIVE	ACCEPTABLE
PROTEIN	NEGATIVE	NEGATIVE	ACCEPTABLE

Z indicates participant's performance score. Typically, the absolute value of Z obtained by the participant gives indications summarized in the following scheme:

- When |Z| is lower or equal to 2,0 "indicates ""satisfactory"" performance and does not generate any signal"
- When |Z| is between 2,0 and 3,0 "indicates ""questionable"" performances and generates a warning signal"
- When |Z| is higher or equal to 3,0 "indicates ""unsatisfactory"" performance and generates an Action signal"

For each parameter, the graphic representation of Shewart is also provided, which allows the evaluation of performance over time in accordance with point B4.2 ISO 17043: 2023 for the purposes of self-improvement.

This test report consists of N ° 15 pages