Chloride – Method Thiocyanate Mercury
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Codice	Composizione
CHEMILAB	REF B81180071	n° 2 flaconi x 16 mL
	REF B81180072	n° 4 flaconi x 16 mL

INTENDED USE
Product for use in the quantitative determination in vitro of the Chloride concentration in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE
Many different methods have been used for the determination of chlorides in serum or plasma. The most important were titrimetric ones such as those of Volhard or Shales-Shales based on the precipitation of insoluble salts (respectively of Ag or Hg) and an indicator to signal the end point. Electrometric and colorimetric methods were also employed.

PRINCIPLE OF THE METHOD
Mercuric thiocyanate colorimetric method.
Chloride ions react with mercuric thiocyanate to form mercuric chloride, undissociated salt, and release thiocyanate ions:

$$Hg(SCN)_2 + 2Cl^- \rightarrow HgCl_2 + 2SCN^-$$

Thiocyanate ions react with ferric ions to form ferric thiocyanate, a coloured compound:

$$3SCN^- + Fe^{3+} \rightarrow Fe(SCN)_3$$

The colour formed is proportional to the chloride content in the sample.

Storage and stability
= storage temperature 2-8°C
Stored at 2-8°C avoiding direct light, the reagents are stable until the expiry date stated on the label. Their slight variation in colour, from batch to batch, does not affect the test results.

Concentrations

Reagente:			
	Conc.	U.M.	
Mercuric thiocyanate	6.00	mmol/L	*GHS05
Ferric nitrate	40.0	mmol/L	
Nitric acid	100	mmol/L	
Dimethylsulfoxide	4.20	mol/L	*GHS08

*Warning: **DANGER**
Contains: Iron nitrate (III) nonaidrato (CAS 7782-61-8) - Mercury dithiocyanate (CAS 592-85-8)
H314 - Causes severe skin burns and eye damage.
H373 - May cause damage to organs through prolonged or repeated exposure.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER/doctor.
P321 - Specific treatment (see on this label).
P501 - Dispose of contents/container in accordance with local/ regional/national/international regulations.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls, calibrators and pipettes with adequate volume

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2.Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements.
Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

PROCEDURE
Quality control
Control sera with a known titer of Chloride are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration
For calibration use the “Calibrator serum Sclavo” Code B35181702

Traceability
The Chloride traceability is reported in the package insert supplied with the “Calibrator Serum”.

SAMPLE
Type of sample and storage
Use serum or plasma free of haemolysis. Serum or plasma must be separated from the clot or red cells respectively within 30 minutes after collection.

PREPARATION OF THE REAGENT
The reagent is liquid, ready for use. After opening, the reagent is stable for 30 days if kept closed at a temperature of 2-8°C away from direct light. Do not mix different batches. Slight variations in colour among batches will not affect test results.

ANALYTICAL TECHNIQUE
For automatic procedures, please refer to the user manual and application notes of the CHEMILAB analyzer. All applications not explicitly approved by Sclavo Diagnostics cannot be guaranteed in terms of performance and must therefore be evaluated by the user.

Calculation of results
The results are automatically calculated by the analyzer using the calibration line. The analyzer automatically picks up the appropriate amount of a primary standard as set in the application method. The calibration line is obtained by interpolating the values obtained with an appropriate calculation algorithm.

REFERENCE RANGE
Serum or plasma:
Males/Females: 98 – 110 mEq/L (98 - 110 mmol/L).
Each laboratory must establish its own normal-range values on the basis of its population.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The reaction is linear up to 150 mEq/L of Chloride. For samples with higher concentrations, repeat the determination with a 1:10 diluted sample in physiological solution and multiply the result by the dilution factor.

Recovery
Accuracy studies have been conducted on normal samples to which known levels of chloride have been added. Data indicate recovery of 99,4%.

Interferences
- Sodium Azide at 2 g/L corresponds to + 41,3 mEq/L of Cl^-
- Sodium salicylate at 40 mg/dL corresponds to + 4,2 mEq/L of Cl^-
- Bromide and iodide interfere stechiometrically

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Precision of the method

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mEq/L	88.9	0.34	0.39	20
High	mEq/L	120	0.39	0.32	20
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mEq/L	82.9	1.11	1.31	20
High	mEq/L	115	2.15	2.15	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is 1.0 mEq/L of chloride in the conditions established for this test.

Comparison between methods
The method for Chloride was compared with a similar commercially available method, analyzing 20 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	-2.02
Slope	0.971
Correlation Coeff. (R)	0.98

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

REFERENCES

1. **Volhard, J**: Prakt. Chem. 9: 217, 1984.
2. **Shales, O. and Shales S.S**.: J Biol. Chem. 140: 879, 1941.
3. **Spandrio, L Panigada C**.: Giorn. It. Chim. 1: 243,1976.
4. **Iwsaki, I., Utsumi S., Hagino K.,OzawaT.**: Bull.Chem.Soc.Jap. 25: 226, 1952.
5. **Spandrio, L. Briganni A**.:Giorn: It. Clin. Chim. 4(3): 345-354,1979.
6. **Pasquinelli, F**.: Diagnostica e tecniche di laboratorio, ed. Rossini, Firenze, 1021-1031,1979.
7. **De Jong, E. B. M.** et al.: Clin. Chem. 26. (8): 1233, 1980.

REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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