

URIC ACID MONO SL

❖ Références/Referenes/ Referencias/ Referências:	Composition du coffret/ Kit composition/ Composición del kit/ Conteúdo da embalagem :
AUML-0420	R 6 x 50 mL
AUML-0500	R 6 x 100 mL
AUML-0250	R 12 x 20 mL
AUML-0427	R 6 x 50 mL + Std 1 x 5 mL
AUML-0497	R 1 x 100 mL + Std 1 x 5 mL
AUML-0507	R 6 x 100 mL + Std 1 x 5 mL
AUML-0707	R 4 x 250 mL + Std 1 x 5 mL



Urée : Aucune interférence significative jusqu'à 5000 mg/dL (832,50 mmol/L).
Acide ascorbique: Aucune interférence significative jusqu'à 20 mg/dL.
Méthyl dopa: Induit des résultats faussement élevés aux concentrations thérapeutiques.

- Les résultats peuvent être faussement abaissés dans les échantillons contenant des niveaux significatifs de NAC (N-Acétyl-Cystéine) , de NAPQI (métabolite de l'acétaminophène (paracétamol)) ou de Méfamizole.

- D'autres substances et médicaments peuvent interférer. Certains d'entre eux sont répertoriés dans les revues publiées par Young.⁽¹³⁻¹⁴⁾

- Pour le diagnostic, les résultats doivent toujours être confrontés aux résultats d'autres tests diagnostiques, aux examens cliniques, et aux données de l'anamnèse du patient.

- Stabilité à bord/ Fréquence de calibration

Stabilité à bord: 28 jours
Fréquence de calibration: 28 jours
 Une nouvelle calibration doit être effectuée après chaque changement de lot de réactif, lorsque les résultats du ou des contrôles de qualité sont hors de l'intervalle établi, et après une opération de maintenance.

❖ Ces performances ont été définies sur un automate ELITech Selectra ProM. Les résultats peuvent varier si le réactif est utilisé sur un automate différent ou en méthode manuelle.
 Les performances obtenues à partir d'applications non validées par ELITech ne peuvent être garanties et doivent être définies par l'utilisateur.

English - EN

❖ INTENDED USE

ELITech Clinical Systems URIC ACID MONO SL is an *in vitro* diagnostic reagent intended for the quantitative determination of Uric Acid in human serum, plasma and urine samples.

CLINICAL SIGNIFICANCE ⁽¹⁻³⁾

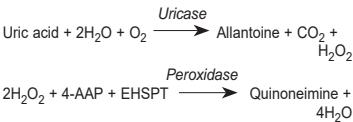
Uric acid is the major product of the catabolism of endogenous and exogenous (dietary) purine nucleosides (adenosine and guanosine). This transformation mainly occurs in the liver. Approximately 75% of uric acid is eliminated by kidneys; the remainder is secreted into the gastrointestinal tract, where it is degraded by bacterial enzymes. Uric acid is not very soluble in water; urate crystals can occur in urines when the concentration is abnormally high. It can also happen in plasma, crystals then deposit essentially in joints, which induce intense inflammatory responses (gout). Some causes for increasing uric acid rate in serum are: increasing of purines synthesis, metabolic disorders (Lesch-Nyhan syndrome for example), nutritional troubles, increasing of nucleic acid turn-over in the case of proliferation of tumor cells, leukaemia, psoriasis, cytotoxic drugs, renal failures... Decreasing of uric acid rate in serum is more uncommon. It can occur in different cases: failure in renal elimination of uric acid (Fanconi syndrome), Hodgkin's disease for example. The quantitation of urinary uric acid is used to define the cause of hyperuricemia (excess purines or renal retention) and define appropriate treatment.

METHOD ⁽⁴⁾

Enzymatic - colorimetric.
 Trinder. End point.

PRINCIPLE ⁽⁴⁾

Enzymatic determination of uric acid according to the following reactions:



EHSPT = N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl) *m*-Toluidine
 4-AAP = Amino-4-antipyrine

❖ COMPOSITION

Reagent: R		
Phosphate buffer, pH 7.0	100	mmol/L
EHSPT	0.72	mmol/L
Ferrocyanide	0.03	mmol/L
Amino-4-antipyrine	0.37	mmol/L
Uricase	≥ 150	U/L
Peroxidase	≥ 12 000	U/L
Sodium azide	< 0,1	%

Standard: Std (Ref : AUML-0427/0497/0507/0707)
 Uric acid 6 mg/dL

Sodium azide	<	357	µmol/L	%
		0.5		

❖ MATERIALS REQUIRED BUT NOT PROVIDED

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Normal saline solution (NaCl 9 g/L).
- General Laboratory equipment.
- Do not use materials that are not required as indicated above.

❖ WARNINGS AND PRECAUTIONS

- These *in vitro* diagnostic devices (reagent and standard) are for professional use only.
- The reagent R and standard contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The standard should be immediately and tightly capped to prevent contamination and evaporation.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

❖ STABILITIES

Store at 2-8 °C and protect from light. Do not freeze.
 Do not use after expiration dates indicated on the vial labels.

On board stability :
 The on-board stability is specific for each analyzer. (Refer to § PERFORMANCE DATA).

❖ PREPARATION

The reagent and standard are ready to use.

❖ PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate deterioration.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the damages of packaging might have an effect on the product performances (leakages, pierced vial).
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the damages of packaging might have an effect on the product performances (leakages, pierced vial).
- Do not use other specimens.

Warnings and precautions
 - According to Good Laboratory Practice, sampling should be performed prior to the administration of drugs. Sampling could lead to false results if performed during or immediately after the administration of some drugs.

- If unpreserved urine is received, add 0.1 mL of 12.5M NaOH to 10 mL of well-mixed urine; mix well. Warming at 60 °C to dissolve precipitate may be needed.

Storage and stability
 - Serum and heparinized plasma samples are stable 3 to 5 days if stored at 2-8 °C, 6 months at -20 °C.
 - Urines are stable 3 days at room temperature. Do not refrigerate urine samples.

REFERENCE VALUES ⁽⁵⁾

	Man	Woman	
Serum, plasma :	3.5 - 7.2	2.6 - 6.0	mg/dL
	208 - 428	155 - 357	µmol/L

Urine :	250 - 750	mg/24 h
	1.48 - 4.43	mmol/24 h
	16.7 - 50.0	mg/dL*
	0.99 - 2.97	mmol/L*

* for an urinary volume of 1.5 L per 24 hours

Note : The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.

❖ PROCEDURE

Manual Procedure	
Wavelength :	546 nm
Optical path :	1 cm
Sample/reagent ratio :	1:40
Temperature :	37 °C

Read against reagent blank.

	CALIBRATION	TEST
Reagent R	1 000 µL	1 000 µL
Standard/ Calibrator	25 µL	-
Sample	-	25 µL

Mix and read the absorbances (A) after an incubation of 5 minutes.

Automatic Procedure

These reagents may be used in several automatic analyzers. For ELITech Selectra Analyzers, validated applications are available on request. For Selectra TouchPro software, use the application included in the barcode available at the end of this insert.

❖ CALCULATION

A Sample x n n = Calibrator/ standard
 A Calibrator/ Standard concentration

Conversion factor : mg/dL x 59.48 = µmol/L
 mg/dL x 0.059 = mmol/L
 mg/dL x 10 = mg/L

Take the dilution factor into account for the calculation of uric acid concentration in urine.

❖ CALIBRATION

For the references AUML-0427/0497/0507/0707: For calibration, use either multiparametric calibrator ELICAL 2 or Uric Acid Standard 6 mg/dL. For the reference AUML-0250 0420/0500: For calibration, use multiparametric calibrator ELICAL 2.

Concentration values of Uric Acid Standard 6 mg/dL and multiparametric calibrator ELICAL 2 are traceable to the reference method ID-MS (Isotope Dilution - Mass Spectrometry).

Calibration frequency : The calibration is specific for each analyzer. (Refer to § PERFORMANCE DATA).

❖ QUALITY CONTROL

To check the accuracy of assays, control sera such as ELITROL I and ELITROL II should be used. These controls must be performed and validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control materials should be used in accordance with local guidelines.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements.

PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProM Analyzers

❖- **Measuring range**
 Determined according to CLSI EP6-A protocol⁽⁶⁾.

a) **Serum/Plasma**
 The measuring range is from 1.50 to 25.00 mg/dL (89 to 1487 µmol/L).
 Samples having greater concentrations should be diluted 1:5 with NaCl 9 g/L solution and re-assayed. This procedure extends the measuring range up to 125.00 mg/dL (7436 µmol/L).

For users with Selectra TouchPro software, the «dilute» function performs the sample dilution automatically. Results take the dilution into account.

b) Urine

The measuring range is from 5.0 to 250.0 mg/dL (0.30 to 14.87 mmol/L).

Samples having greater concentrations should be diluted 1:5 with NaCl 9 g/L solution and re-assayed. This procedure extends the measuring range up to 800.0 mg/dL (47.59 mmol/L).

For users with Selectra TouchPro software, the «dilute» function performs the sample dilution automatically. Results take the dilution into account.

- **Limit of Detection (LoD) and Limit of Quantification (LoQ)**
 Determined according to CLSI EP17-A protocol⁽⁷⁾.

a) **Serum/Plasma**
 LoD = 0.09 mg/dL (5 µmol/L)
 LoQ = 1.00 mg/dL (59 µmol/L)

b) **Urine**
 LoD = 0.6 mg/dL (0.04 mmol/L)
 LoQ = 5.0 mg/dL (0.30 mmol/L)

- **Precision**
 Determined according to CLSI EP5-A2 protocol⁽⁸⁾.

a) **Serum/Plasma**

		Mean	Within-run	Total
	n	mg/dL	µmol/L	CV (%)
Low level	80	2.41	143	0.5 2.8
Medium level	80	4.95	294	0.7 2.3
High level	80	6.86	408	0.7 2.2

b) **Urine**

		Mean	Within-run	Total
	n	mg/dL	mmol/L	CV (%)
Low level	80	10.3	0.61	1.8 6.6
Medium level	80	23.9	1.42	1.1 3.8
High level	80	77.9	4.63	1.2 3.3

- Correlation

a) **Serum/Plasma**
 A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-approved system equipment (Uricase method) on 100 human sera samples according to CLSI EP9-A2 protocol⁽⁹⁾. The values were between 1.55 and 23.94 mg/dL (92 and 1424 µmol/L). The parameters of the linear regressions are as follows:
 Correlation coefficient : (r) = 0.999
 Linear regression: y = 1.044 x - 0.04 mg/dL (2 µmol/L)

b) **Urine**
 A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-approved system equipment (Uricase method) on 49 urine samples according to CLSI EP9-A2 protocol⁽¹¹⁾. The values were between 5.6 and 220.2 mg/dL (0.33 and 13.10 mmol/L). The parameters of the linear regressions are as follows:
 Correlation coefficient: (r) = 0.996
 Linear regression: y = 1.061 x + 0.1 mg/dL (0.01 mmol/L)

Español - ES

❖ USO PREVISTO

ELITech Clinical Systems URIC ACID MONO SL es un reactivo de diagnóstico *in vitro* diseñado para la determinación cuantitativa del ácido úrico en muestras de suero, plasma y orina humanas.

SIGNIFICADO CLÍNICO ⁽¹⁻³⁾

El ácido úrico es el producto final del catabolismo de los nucleótidos purínicos (adenosina y guanina) endógeno y exógeno (de origen alimenticio). Esta transformación ocurre fundamentalmente en el hígado. Aproximadamente el 75 % del ácido úrico se elimina por los riñones; el resto se libera en el tracto gastrointestinal donde es degradado por las enzimas bacterianas. El ácido úrico es muy poco soluble en agua; en la orina pueden aparecer cristales de urato cuando la concentración es anormalmente alta. Este fenómeno puede también ocurrir en el plasma, los cristales se depositan entonces fundamentalmente en las articulaciones provocando inflamaciones dolorosas (gota). Entre las causas de aumento de las tasas de ácido úrico en el suero pueden ser mencionadas: aumento de la síntesis de purinas, desórdenes metabólicos (por ejemplo el Síndrome de Lesch-Nyhan), problemas nutricionales, aumento del recambio de ácidos nucleicos especialmente en el caso de una proliferación de células tumorales, leucemia, psoriasis, drogas citotóxicas, fallo renal... La disminución de la concentración de ácido úrico en el suero es menos frecuente. Puede ocurrir en diferentes casos: fallo en la eliminación renal del ácido úrico (síndrome de Fanconi), enfermedad de Hodgkin por ejemplo. La cuantificación del ácido úrico urinario es utilizada para determinar la causa de la hiperuricemia (exceso de purinas o insuficiencia renal) y definir un tratamiento adecuado.

- **Limitations/Interferences**
 - Do not use visibly turbid or hemolyzed samples.

- Do not report results outside of the usable range.

a) **Serum/ plasma**
 - Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol⁽¹⁰⁾ and SFBC recommendations⁽¹¹⁾. Recovery is within ±10% of initial value at uric acid concentration of 2.52 mg/dL and 7.56 mg/dL.
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin: No significant interference up to 14.8 mg/dL (252 µmol/L).
Hemoglobin: No significant interference up to 50 mg/dL.
Glucose: No significant interference up to 500 mg/dL (27.75 mmol/L).
Triglycerides: No significant interference up to 2095 mg/dL (23.67 mmol/L).
Turbidity: Interference occurs at all levels of Intralipid®
Ascorbic acid: Significant interference on samples containing ascorbic acid.
Methyl-dopa: No significant interference up to 1 mg/dL.
Calcium dobesilate: Induces falsely low results on individuals taking calcium dobesilate.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenström's macroglobulinemia) can cause unreliable results.⁽¹²⁾

- Results can be falsely lowered by significant levels in sample of NAC (N-Acetyl-Cysteine), NAPQI (metabolite of acetaminophene (paracetamol)) or metazolam.

- Many other substances and drugs may interfere. Some of them are listed in reviews published by Young.⁽¹³⁻¹⁴⁾

- The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

URIC ACID MONO SL

❖ Références/Referenes/ Referencias/ Referências:	Composition du coffret/ Kit composition/ Composición del kit/ Conteúdo da embalagem :
AUML-0420	R 6 x 50 mL
AUML-0500	R 6 x 100 mL
AUML-0250	R 12 x 20 mL
AUML-0427	R 6 x 50 mL + Std 1 x 5 mL
AUML-0497	R 1 x 100 mL + Std 1 x 5 mL
AUML-0507	R 6 x 100 mL + Std 1 x 5 mL
AUML-0707	R 4 x 250 mL + Std 1 x 5 mL



Note : Se recomienda que cada laboratorio establezca y mantenga sus propios valores de referencia con respecto a la población destinataria. Los datos aquí proporcionados son únicamente una indicación.

❖ PROCEDIMIENTO

Procedimiento manual
 Longitud de onda : 546 nm
 Trayectoria óptica : 1 cm
 Ratio muestra/reactivo : 1:40
 Temperatura : 37 °C
 Leer contra blanco reactivo.

	CALIBRACIÓN	PRUEBA
Reactivo R	1 000 µL	1 000 µL
Estándar/ Calibrador	25 µL	-
Muestra	-	25 µL

Mezclar y leer las absorbancias (A) después de una incubación de 5 minutos.

Procedimiento automático

Estos reactivos pueden ser utilizados en varios equipos. Para los equipos ELITech Selectra, las aplicaciones validadas están disponibles sobre pedido. Para el software Selectra TouchPro, use la aplicación incluida en el código de barras disponible al final de este inserto.

❖ CÁLCULO

A Muestra x n n = concentración del estándar/ calibrador

Factor de conversión: mg/dL x 59.48 = µmol/L
 mg/dL x 0.059 = mmol/L
 mg/dL x 10 = mg/L

Para el cálculo de la concentración de ácido úrico en las orinas, tomar en cuenta el factor de dilución de la orina.

❖ CALIBRACIÓN

Para las referencias AUML-0427/0497/0507/0707: Para la calibración, utilizar ya sea el calibrador multiparamétrico ELICAL 2 o el estándar Uric Acid Standard 6 mg/dL.

Para la referencia AUML-0250/0420/0500: Para la calibración, utilizar el calibrador multiparamétrico ELICAL 2.

Los valores del estándar Uric Acid Standard 6 mg/dL y el calibrador multiparamétrico ELICAL 2 son trazable al método de referencia ID-MS (Dilución isotópica - Espectrometría de masas).

Frecuencia de calibración : la frecuencia de calibración es específica para cada equipo (referirse al § DATOS DE RENDIMIENTO).

❖ CONTROL DE CALIDAD

Para asegurar la exactitud de los resultados, sueros de control tales como ELITROL I y ELITROL II deben ser utilizados. Los controles deben ser realizados y validados antes de que las muestras del paciente sean probadas. La frecuencia de control debe ser al menos una vez al día, después de cada calibración y debe ser adaptada a los procedimientos de control de calidad de cada laboratorio y las exigencias regulatorias. Los resultados deben estar dentro del rango analítico definido. Si los valores quedan fuera del rango analítico definido, cada laboratorio deberá de tomar las medidas correctivas. Los materiales de control de calidad deben ser usados conforme a las directivas locales.

TRATAMIENTO DE LOS RESIDUOS

Todos los materiales de desecho deben eliminarse de acuerdo con los requisitos reglamentarios locales, estatales y federales.

DATOS DE RENDIMIENTO a 37 °C en equipo ELITech Clinical Systems Selectra ProM

❖- **Rango analítico**
 Determinado de acuerdo al protocolo CLSI EP6-A⁽⁶⁾.

a) **Suero/ plasma**
 El rango analítico se encuentra entre 1,50 a 25,00 mg/dL (89 a 1487 µmol/L).
Bilirrubina no conjugada: No hay interferencia significativa hasta 30,0 mg/dL (513 µmol/L).
Bilirrubina conjugada: No hay interferencia significativa hasta 14,8 mg/dL (252 µmol/L).
Hemoglobina: No hay interferencia significativa hasta 50 mg/dL.
Glucosa: No hay interferencia significativa hasta 500 mg/dL (27,75 mmol/L).
Triglicéridos: No hay interferencia significativa hasta 2095 mg/dL (23,67 mmol/L).
Turbidez: Las interferencias ocurren a todos los niveles de Intralipid®.

Para los usuarios del software Selectra TouchPro, la función «diluir» realiza la dilución de las muestras automáticamente. Los resultados toman en cuenta la dilución.

b) **Orina**
 El rango analítico se encuentra entre 5,0 a 250,0 mg/dL (0,30 a 14,87 mmol/L).
 Las muestras que tengan concentraciones mayores deben diluirse 1:5 con una solución de NaCl 9 g/L y volver a analizarse. Este procedimiento amplía el rango analítico hasta 800,0 mg/dL (47,59 mmol/L)

Para los usuarios del software Selectra TouchPro, la función «diluir» realiza la dilución de las muestras automáticamente. Los resultados toman en cuenta la dilución.

- **Límite de detección (LoD), límite de Cuantificación (LoQ)**
 Determinados de acuerdo al protocolo CLSI EP17-A⁽⁷⁾.

a) **Suero/ plasma**
 LoD = 0,09 mg/dL (5 µmol/L)
 LoQ = 1,00 mg

AUML-0420	R	6 x 50 mL		
AUML-0500	R	6 x 100 mL		
AUML-0250	R	12 x 20 mL		
AUML-0427	R	6 x 50 mL	+ Std	1 x 5 mL
AUML-0497	R	1 x 100 mL	+ Std	1 x 5 mL
AUML-0507	R	6 x 100 mL	+ Std	1 x 5 mL
AUML-0707	R	4 x 250 mL	+ Std	1 x 5 mL



PIT-AUML-4-v22 (01/2019)

b) Urina

Um estudo comparativo foi realizado entre um ELITech Clinical Systems Selectra ProM e outro sistema de um equipamento aprovado pela FDA (método Uricase) em 49 amostras de urina e de acordo com o protocolo CLSI EP9-A2⁽⁹⁾.

Os valores repartiram-se entre 5,6 e 220,2 mg/dL (0,33 e 13,10 mmol/L).

Os parâmetros da recta de regressão são os seguintes:

Coefficiente de correlação : (r) = 0,996

Linha de regressão: $y = 1,061 x + 0,1 \text{ mg/dL}$

(0,01 mmol/L)

- Limitações/Interferências

- Não utilize amostras visivelmente turvas ou hemolizadas.

- Não relatam resultados fora do alcance útil.

a) Soro plasma

- Foram realizados testes para determinar o nível de interferência de diferentes compostos segundo as recomendações de protocolo do CLSI EP7-A2⁽¹⁰⁾ e recomendações da SFBC⁽¹¹⁾. Recuperação dentro de $\pm 10\%$ do valor inicial de concentração de ácido úrico de 2,52 e 7,56 mg/dL.

Bilirrubina não conjugada: Nenhuma interferência significativa até 30 mg/dL (513 $\mu\text{mol/L}$).

Bilirrubina conjugada: Nenhuma interferência significativa até 14,8 mg/dL (252 $\mu\text{mol/L}$).

Hemoglobina: Nenhuma interferência significativa até 50 mg/dL.

Glucose: Nenhuma interferência significativa até 500 mg/dL (27,75 mmol/L)

Triglicéridos: Nenhuma interferência significativa até 2095 mg/dL (23,67 mmol/L).

Turvação: Interferência ocorre em todos os níveis de Intralipid®

Ácido ascórbico: interferência significativa em amostras contendo ácido ascórbico.

Metildopa: Nenhuma interferência significativa até 1 mg/dL.

Dobesilato de cálcio: Induz resultados falsamente baixos em indivíduos que tomam dobesilato cálcio.

- Em casos muito raros, as gamopatias monoclonais (mieloma múltiplo), em particular, tipo IgM (macroglobulinemia de Waldenström) podem causar resultados não confiáveis.⁽¹²⁾

- Os resultados podem ser falsamente reduzidos em níveis significativos em amostra de NAC (N-Acetyl-Cysteine), NAPQI (metabolite of acetaminophene (paracetamol)) ou dipirona.

- Muitas outras substâncias e drogas podem interferir. Alguns deles estão referenciados em análises publicadas por Young.⁽¹³⁻¹⁴⁾

- Os resultados deste teste só devem ser interpretados em conjunto com outros resultados de testes de diagnóstico, que constem no historico médico e clínico do paciente.

b) Urina

- Foram realizados testes para determinar o nível de interferência de diferentes compostos segundo as recomendações de protocolo do CLSI EP7-A2⁽¹⁰⁾. Recuperação dentro de $\pm 10\%$ do valor inicial de concentração de ácido úrico de 10,0 e 75,0 mg/dL.

Bilirrubina conjugada: Nenhuma interferência significativa até 29,5 mg/dL (504,6 $\mu\text{mol/L}$).

Hemoglobina: Nenhuma interferência significativa até 300 mg/dL.

Urea: Nenhuma interferência significativa até 5000 mg/dL (832,5 mmol/L)

Ácido ascórbico: Nenhuma interferência significativa até 20 mg/dL.

Metildopa: Em concentrações terapêuticas induz resultados falsamente elevados.

- Os resultados podem ser falsamente reduzidos em níveis significativos em amostra de NAC (N-Acetyl-Cysteine), NAPQI (metabolite of acetaminophene (paracetamol)) ou dipirona.

- Muitas outras substâncias e drogas podem interferir. Alguns deles estão referenciados em análises publicadas por Young.⁽¹³⁻¹⁴⁾

- Os resultados deste teste só devem ser interpretados em conjunto com outros resultados de testes de diagnóstico, que constem no historico médico e clínico do paciente.

- Estabilidade a bordo / frequência de calibração

Estabilidade a bordo: 28 dias

Frequência de calibração: 28 dias

Uma nova calibração deve ser efetuada após cada mudança de lote de reagente, quando os resultados do(s) controle(s) de qualidade estiverem fora do intervalo estabelecido e após uma operação de manutenção.

☛ *Estes desempenhos foram obtidos utilizando o analisador ELITech Selectra ProM. Os resultados podem variar se um instrumento diferente ou um procedimento manual for usado.*

Os desempenhos de aplicações não validados pela ELITech não são garantidos e devem ser definidos pelo usuário.

**BIBLIOGRAPHIE/BIBLIOGRAPHY
BIBLIOGRAFÍA/BIBLIOGRAFIA**

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**☛ SYMBOLES/SYMBOLS/
SÍMBOLOS/SÍMBOLOS**

- Les symboles utilisés sont décrits dans la norme ISO-15223-1 hormis ceux présentés ci-dessous.

- Symbols used are defined on ISO-15223-1 standard, except those presented below.

- Los símbolos utilizados son descritos en la norma ISO-15223-1 a la excepción de los presentados a continuación.

- Os símbolos utilizados são definidos na norma ISO-15223-1, exceto os apresentados abaixo.

CONT	Contient Content Contiene Conteúdo
R	Réactif Reagent Reactivo Reagente
Std	Standard Standard Estándar Padrão
CE	Conformité Européenne European Conformity Conformidad Europea Conformidade Europeia

Note/Nota

- Uniquement pour la réf. **AUML-0250**, utilisée avec le logiciel Selectra TouchPro.

- Only for ref. **AUML-0250**, used with Selectra TouchPro software.

- Únicamente para la ref. **AUML-0250**, utilizada con el software Selectra TouchPro.

- Somente para ref. **AUML-0250**, usado com o Selectra TouchPro.



Uric Acid 0
660 PIT-AUML

