

English - EN

INTENDED USE

ELITech Clinical Systems UREA UV SL es an *in vitro* diagnostic reagent intended for the quantitative determination of urea in human serum, plasma and urine samples on analyzers or semi-automatic analyzers. The standard is intended for the calibration of the reagent.

These *in vitro* diagnostic devices are for professional use only.

CLINICAL SIGNIFICANCE ⁽¹⁻³⁾

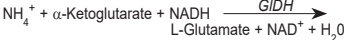
Urea is the major byproduct of protein catabolism. It originates from the liver and is mostly excreted through the kidneys. Blood urea concentrations can be increased by numerous factors linked to prerenal causes (increased protein catabolism as in hemorrhage into gastrointestinal tract, shock), renal causes (acute or chronic renal diseases) or postrenal causes (obstruct to urine flow). Uremia is also increased by high-protein diet or dehydration. A decreased serum urea concentration can be observed during pregnancy or with a low-protein diet. In practice, urea measurement in serum is performed to help diagnose kidney diseases, to monitor treatments against these pathologies or to monitor renal function during treatments that may impair this function. Due to many non-renal causes for serum level variation, urea is however a less good marker of kidney function than creatinine.

LIMITATION OF USE

The quantitative assay of urea alone cannot be used to diagnose a disease or a specific pathology. The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE ⁽⁴⁾

Urease/GIDH - Kinetic.



GIDH = Glutamate dehydrogenase

COMPOSITION

Reagent 1 : R1

Tris buffer, pH 7.60 (37 °C)

α-Ketoglutarate	9 mmol/L
Urease	≥ 8100 U/L
GIDH	≥ 1350 U/L
Sodium azide	< 0.1% (w/w)

Reagent 2 : R2

NADH	1.3 mmol/L
Sodium azide	< 0.1% (w/w)

Standard: Std (Ref : URSL-0427/0507)

Urea	50 mg/dL
	8.33 mmol/L

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS FOR USE AND WARNINGS

- Consult Safety Data Sheet (SDS) for a proper handling.
- The reagents 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.
- Do not interchange reagent vials from different kits.

STABILITY

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

The standard should be immediately and tightly capped to prevent contamination and evaporation. **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 contamination or damage (e.g. particle matter).
- Damage to the product container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimen ⁽³⁾

- Serum.
 - Plasma (lithium heparin).
 - Urine.
 - Using any other specimen type should be validated by the laboratory.
- Warnings and precautions**
- Addition of thymol as preservative is not recommended as it inhibits urease activity ⁽³⁾
 - Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.
- Storage and stability** ^(2,3)
- Serum/plasma
- 24h at room temperature.

- 1 week at 2-8°C.
- 3 months at -20°C.
- Urine
- 4 days at 2-8°C provided bacterial contamination is avoided.

REFERENCE VALUES ⁽²⁾

<i>Serum/plasma</i>	mg/dL	mmol/L
Children <1 year old	8.6 - 40.7	1.4 - 6.8
Children 1-18 years old	10.7 - 38.6	1.8 - 6.4
Adults (18 - 60 years)	12.9 - 42.9	2.14 - 7.14
Adults (60 - 90 years)	17.2 - 49.3	2.86 - 8.21
Adults (>90 years)	21.4 - 66.5	3.57 - 11.07
<i>Urine (24h - collection)</i>	g/24h	mol/24 h
Adults	26 - 43	0.43 - 0.71
	For a urinary volume of 1.5 L/24h mg/dL	mmol/L
	1 700 - 2 900	290 - 470

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.

❖INSTALLATION AND USE

For use on Selectra Pro analyzers :

- Consult operator manual.

- **Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer.** Refer to Instructions For Use of ACID SOLUTION & SYSTEM CLEANING SOLUTION for adequate programming (See PIT-SOL).

PROCEDURE

Manual Procedure

<i>Wavelength :</i>	340 nm
<i>Optical path :</i>	1 cm
<i>Sample/ Reagent ratio :</i>	1:100
<i>Temperature:</i>	37 °C

Urine samples must be diluted 1:20 with NaCl 9 g/L solution before measurement.

Read against distilled water.

Working reagent (4 volumes of R1 + 1 volume of R2)	1000 µL
Sample	10 µL

Mix and after 30 seconds incubation, read absorbance at 30 seconds intervals during 90 seconds. Calculate the change of absorbances per minute (ΔA/min).

Automatic Procedure

These reagents may be used on 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.

Urine samples must be diluted 1:20 with NaCl 9 g/L solution before measurement. For users of Selectra TouchPro software, urine dilution is performed automatically.

CALCULATION

ΔA/min. Sample	x n	n = Calibrator/ standard concentration
ΔA/min. Calibrator/ Standard		

For the calculation of urea concentration in urine, multiply the result by the dilution factor (20). For users of Selectra TouchPro software, the results take the dilution factor into account.

Conversion factor : mg/dL x 0.1665 = mmol/L

❖CALIBRATION

ELICAL 2 and Urea Standard 50 mg/dL are traceable to ID-MS (Isotope Dilution - Mass Spectrometry) reference method.

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

QUALITY CONTROL

It is recommended that quality control sera such as ELITROL I and ELITROL II be used to monitor the performance of the assay. Controls have to be performed :

- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra ProM, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

a) Serum/Plasma

10 - 300 mg/dL (1.67 - 49.95 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 1 500 mg/dL (249.75 mmol/L).

Do not report results outside this extended range.

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

b) Urine

200 - 6 000 mg/dL (33 - 999 mmol/L)

Do not report results outside the measuring range.

Limit of Detection (LoD) and Limit of Quantification (LoQ)

a) Serum/Plasma

LoD = 1.5 mg/dL (0.25 mmol/L)

LoQ = 5.0 mg/dL (0.83 mmol/L)

b) Urine

LoD = 18 mg/dL (3 mmol/L)

LoQ = 200 mg/dL (33 mmol/L)

- Precision

Imprecision data has been obtained on 2 Selectra ProM analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented below :

a) Serum/Plasma

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	18.0	3.00	1.6	3.2
Level 2	80	59.0	9.82	1.2	2.2
Level 3	80	144.6	24.08	1.0	2.1

b) Urine

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	482	80	1.7	3.8
Level 2	80	1165	194	0.6	3.1
Level 3	80	2587	431	0.4	3.6

- Correlation

a) Serum/Plasma

A comparative study has been performed between UREA UV SL reagent on a Selectra ProM analyzer and a similar commercially available system on 98 human serum samples.

The sample concentrations ranged from 12.5 to 285.5 mg/dL (2.08 - 47.54 mmol/L).

The results are as follows :

Correlation coefficient : (r) = 1.000

Linear regression: y = 0.993x - 0.1 mg/dL (0.02 mmol/L)

b) Urine

A comparative study has been performed between UREA UV SL reagent on a Selectra ProM analyzer and a similar commercially available system 53 human urine samples.

The sample concentrations ranged from 203 to 5 569 mg/dL (34 - 927 mmol/L).

The results are as follows :

Correlation coefficient : (r) = 0.999

Linear regression: y = 1.000x + 52 mg/dL (9 mmol/L)

- Limitations/Interferences

a) Serum/Plasma

Studies have been performed to determine the level of interference from different compounds. The following urea levels were tested: 15.0 mg/dL and 60.1 mg/dL. No significant interference is defined by a recovery ≤±10% of the initial value. Unconjugated Bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L). Conjugated Bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L). Turbidity: No significant interference up to 614 mg/dL (6.94 mg/dL) Triglyceride equivalent. Hemoglobin: No significant interference up 500 mg/dL. Ascorbic acid: No significant interference up 20.0 mg/dL. Methyl dopa: No significant interference up 1.0 mg/dL.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenström's macroglobulinemia) can cause unreliable results.⁽⁴⁾

- Many other substances and drugs may interfere. Some of them are listed in reviews published by Young.⁽⁶⁻⁷⁾

b) Urine

- Studies have been performed to determine the level of interference from different compounds. The following urea levels were tested: 1 500 mg/dL and 3 000 mg/dL. No significant interference is defined by a recovery ≤±10% of the initial value.

Conjugated Bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L).

Hemoglobin: No significant interference up 500 mg/dL.

Ascorbic acid: No significant interference up 20.0 mg/dL.

Uric acid: No significant interference up 120 mg/dL (7.14 mmol/L).

pH: No significant interference for pH values ranging between 2.5 and 12.0.

- Many other substances and drugs may interfere. Some of them are listed in reviews published by Young.⁽⁶⁻⁷⁾

- On board stability/Calibration frequency

On Board Stability: 14 days

Calibration frequency: 7 days

Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

These performances have been obtained using ELITech Selectra ProM analyzer. Results may vary if a different instrument or a manual procedure is used. The performances of applications not validated by ELITech are not warranted and must be defined by the user.

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements. By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

TECHNICAL ASSISTANCE

Contact your local distributor or ELITech Clinical Systems SAS (ccsupport@elitechgroup.com).

Español - ES

USO PREVISTO

ELITech Clinical Systems UREA UV SL es un reactivo de diagnóstico *in vitro* diseñado para la determinación cuantitativa de la urea en muestras de suero, plasma y orina humanas en equipos automatizados o equipos semiautomáticos. El estándar está diseñado para la calibración del reactivo. Estos dispositivos de diagnóstico *in vitro* están destinados únicamente para los profesionales.

SIGNIFICADO CLÍNICO ⁽¹⁻³⁾

La urea es el principal subproducto del metabolismo proteico. Se origina en el hígado y se excreta principalmente a través de los riñones.

Las concentraciones de urea en sangre pueden incrementarse por numerosos factores relacionados con causas prerenales (aumento del catabolismo de las proteínas como en la hemorragia en el tracto gastrointestinal, shock) o causas renales (enfermedades renales agudas o crónicas) o causas post renales (obstrucción del flujo de orina). La uremia también se incrementa por la dieta alta en proteínas o la deshidratación. Se puede observar una disminución de la concentración sérica de urea durante el embarazo o con una dieta baja en proteínas.

En la práctica, la medición de la urea en suero se realiza para ayudar a diagnosticar enfermedades renales, para controlar los tratamientos contra estas patologías o para controlar la función renal durante los tratamientos que pueden afectar esta función. Debido a muchas causas no renales para la variación del nivel sérico, sin embargo la urea es un marcador menos bueno de la función renal que la creatinina.

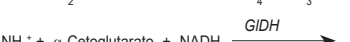
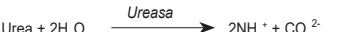
LÍMITE DE UTILIZACIÓN

La cuantificación de la urea no puede ser utilizado solo para diagnosticar una enfermedad o patología específica.

Los resultados siempre deben compararse con los resultados de otras pruebas de diagnóstico, exámenes clínicos y el historial médico del paciente.

MÉTODO & PRINCIPIO ⁽⁴⁾

Urease/GIDH – Cinética.



GIDH = Glutamato deshidrogenasa

COMPOSICIÓN

Reactivo 1 : R1

Tampón Tris, pH 7.60 (37 °C)

α-Cetoglutarato	9 mmol/L
Ureasa	≥ 8100 U/L
GIDH	≥ 1350 U/L
Azida sódica	< 0.1 % (p/p)

Reactivo 2 : R2

NADH	1.3 mmol/L
Azida sódica	< 0.1 % (p/p)

Estándar : Std (Ref : URSL-0427/0507)

Urea	50 mg/dL
	8.33 mmol/L

MATERIALES REQUERIDOS PERO NO INCLUIDOS

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Solución salina normal (NaCl 9 g/L).
- Equipos automatizados o equipos semiautomáticos.
- Equipamiento general de laboratorio (p. ej. pipeta).
- No utilice materiales que no se requieren, tal como se indica anteriormente.

PRECAUCIONES DE USO Y ADVERTENCIAS

- Consulte la Hoja de Datos de Seguridad (SDS) para un manejo adecuado.

- Los reactivos contienen azida sódica que puede reaccionar con el plomo o el cobre de la tubería y formar potencialmente azidas metálicas explosivas. Cuando se elimine el reactivo enjuague con agua abundantemente para prevenir la acumulación de azidas.

- Tome las precauciones normales y respete las buenas prácticas de laboratorio.
- Para evitar contaminaciones utilizar equipo nuevo o completamente limpio.
- No intercambie los frascos de reactivos de diferentes kits.

ESTABILIDAD

Conservar a 2-8 °C y protegidos de la luz. No congelar.

No utilice después de la fecha de caducidad indicada en la etiqueta de los frascos.

El estándar debe cerrarse inmediatamente y correctamente para evitar contaminación y evaporación.

Estabilidad en el equipo:

La estabilidad es específica para cada equipo. (Referirse al § DATOS DE RENDIMIENTO).

PREPARACIÓN

El reactivo y el estándar están listos para su uso.

DETERIORACIÓN DEL PRODUCTO

- El producto debe ser claro. Turbidez indicaría deterioro.
- No utilice el producto si este presenta signos evidentes de contaminación o deterioro (p. ej partículas).
- Un frasco dañado puede tener un impacto en el rendimiento del producto. No utilice el producto si este tiene signos físicos de deterioro (p. ej, fugas, frasco perforado).

MUESTRAS

Muestras requeridas ⁽³⁾

- Suero
 - Plasma (heparina de litio).
 - Orina.
 - El uso de cualquier otro tipo de muestra debe ser validado por el laboratorio.
- Advertencias y precauciones**
- No se recomienda la adición de timol como conservador, ya que inhibe la actividad de la ureasa. ⁽³⁾
 - Las muestras deben tomarse de acuerdo con las Buenas Prácticas de Laboratorio y las guías apropiadas establecidas.

Conservación y estabilidad ^(2,3)

Suero/Plasma

- 24h a temperatura ambiente.

- 1 semana a 2-8 °C

- 3 meses a -20 °C

Orina

- 4 días a 2-8 °C en ausencia de contaminación bacteriana.

VALORES DE REFERENCIA ⁽²⁾

<i>Suero/plasma</i>	mg/dL	mmol/L
Niños <1 años	8.6 - 40.7	1.4 - 6.8
Niños 1-18 años	10.7 - 38.6	1.8 - 6.4
Adultos (18 - 60 años)	12.9 - 42.9	2.14 - 7.14
Adultos (60 - 90 años)	17.2 - 49.3	2.86 - 8.21
Adultos (> 90 años)	21.4 - 66.5	3.57 - 11.07
<i>Orina (recolectada de 24h)</i>	g/24h	mol/24 h
Adultos	26 - 43	0.43 - 0.71
	Para un volumen de orina de 1.5 L/24h mg/dL	mmol/L
	1 700 - 2 900	290 - 470

***Nota :** Los valores anteriores son solo indicativos. Se recomienda que cada laboratorio establezca y mantenga sus propios valores de referencia en relación con la población destinataria.*

❖INSTALACIÓN Y UTILIZACIÓN

Para uso en equipos Selectra Pro :

- Consulte el manual del usuario.

- **Instrucciones**