

# INSTRUCTIONS FOR USE

# CREA

VITROS Chemistry Products CREA Slides

Creatinine for GENs 80 and above

REF 680 2584

## Intended Use

For *in vitro* diagnostic use only.  
VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.

## Summary and Explanation of the Test

Serum creatinine and urinary creatinine excretion is a function of lean body mass in normal persons and shows little or no response to dietary changes. The serum creatinine concentration is higher in men than in women. Since urinary creatinine is excreted mainly by glomerular filtration, with only small amounts due to tubular secretion, serum creatinine and a 24-hour urine creatinine excretion can be used to estimate the glomerular filtration rate.

Serum creatinine is increased in acute or chronic renal failure, urinary tract obstruction, reduced renal blood flow, shock, dehydration, and rhabdomyolysis. Causes of low serum creatinine concentration include debilitation and decreased muscle mass. Exercise may cause an increased creatinine clearance. The creatinine clearance rate is unreliable if the urine flow is low.

## Principles of the Procedure

The VITROS CREA Slide method is performed using the VITROS CREA Slides and the VITROS Chemistry Products Calibrator Kit 1 on VITROS 250/350, 950, and 5,1 FS Chemistry Systems.

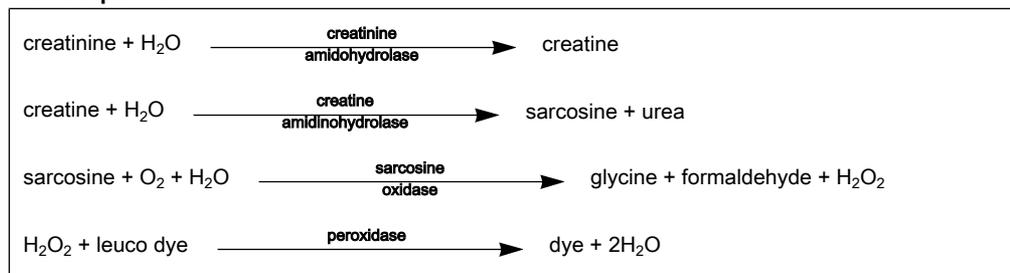
The VITROS CREA Slide is a multilayered, analytical element coated on a polyester support.

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Creatinine diffuses to the reagent layer, where it is hydrolyzed to creatine in the rate-determining step. The creatine is converted to sarcosine and urea by creatine amidinohydrolase. The sarcosine, in the presence of sarcosine oxidase, is oxidized to glycine, formaldehyde, and hydrogen peroxide. The final reaction involves the peroxidase-catalyzed oxidation of a leuco dye to produce a colored product.

Following addition of the sample, the slide is incubated. During the initial reaction phase, endogenous creatine in the sample is oxidized. The resulting change in reflection density is measured at 2 time points.

The difference in reflection density is proportional to the concentration of creatinine present in the sample.

### Reaction Sequence



## Test Type and Conditions

### Test Type and Conditions for CREA

Test Type	VITROS System	Approximate Incubation Time	Temperature	Wavelength	Sample Drop Volume
Two-point rate	5,1 FS, 950, 250/350	5.0 minutes	37 °C (98.6 °F)	670 nm	6 µL

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Warnings and Precautions

## Warnings and Precautions

For *in vitro* diagnostic use only.

Take care when handling materials and samples of human origin. Since no test method can offer complete assurance that infectious agents are absent, consider all clinical specimens, controls, and calibrators potentially infectious. Handle specimens, solid and liquid waste, and test components in accordance with local regulations and CLSI Guideline M29<sup>1</sup> or other published biohazard safety guidelines.

For specific warnings and precautions for calibrators, quality control materials, and other components, refer to the Instructions for Use for the appropriate VITROS product, or to other manufacturer's product literature.

## Reagents

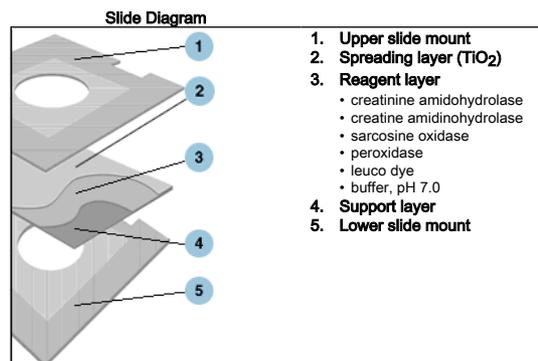
### Slide Ingredients

#### Reactive Ingredients per cm<sup>2</sup>

Creatinine amidohydrolase (*Flavobacterium sp.*, E.C.3.5.2.10) 0.20 U; creatine amidohydrolase (*Flavobacterium sp.*, E.C.3.5.3.3) 4.7 U; sarcosine oxidase (*Bacillus sp.*, E.C.1.5.3.1) 0.55 U; peroxidase (horseradish root, E.C.1.11.1.7) 1.6 U and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl)imidazole (leuco dye) 32 µg.

#### Other Ingredients

Pigment, binders, surfactants, stabilizer, scavenger, chelator, buffer, dye solubilizer and cross-linking agent.



### Reagent Handling

**Caution:** Do not use slide cartridges with damaged or incompletely sealed packaging.

- Inspect the packaging for signs of damage.
- Be careful when opening the outer packaging with a sharp instrument so as to avoid damage to the individual product packaging.

### Reagent Preparation

**IMPORTANT:** The slide cartridge must reach room temperature, 18–28 °C (64–82 °F), before it is unwrapped and loaded into the slide supply.

1. Remove the slide cartridges from storage.
2. Warm the wrapped cartridge at room temperature for 30 minutes when taken from the refrigerator or 60 minutes from the freezer.
3. Unwrap and load the cartridge into the slide supply.

**Note:** Load the cartridges within 24 hours after they reach room temperature, 18–28 °C (64–82 °F).

### Reagent Storage and Stability

VITROS CREA Slides are stable until the expiration date on the carton when they are stored and handled as specified.

#### Reagent Storage and Stability for CREA

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	≤ 4 weeks
	Frozen	≤ -18 °C (≤ 0 °F)	Until expiration date
Opened	On-analyzer	System turned on	≤ 2 weeks
	On-analyzer	System turned off	≤ 2 hours

Verify performance with quality control materials:

- If the system is turned off for more than 2 hours.
- After reloading cartridges that have been removed from the slide supply and stored for later use.

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## Specimen Requirements

## Creatinine for GENs 80 and above

### Specimen Requirements

**WARNING:** Handle specimens as biohazardous material.

#### Specimens Recommended

- Serum
- Plasma<sup>2</sup>: Heparin
- Urine

**IMPORTANT:** Certain collection devices have been reported to affect other analytes and tests.<sup>3</sup> Confirm that your collection devices are compatible with this test.

#### Specimens Not Recommended

Do not use specimens obtained through catheters used to infuse hyperalimentation fluid. Refer to "Limitations of the Procedure."

#### Serum and Plasma

##### *Specimen Collection and Preparation*

Collect specimens using standard laboratory procedures.<sup>4, 5</sup>

**Note:** For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

##### **Patient Preparation**

No special patient preparation is necessary.

##### **Special Precautions**

Centrifuge specimens and remove the serum or plasma from the cellular material within 4 hours of collection.<sup>6</sup>

##### *Specimen Handling and Storage*

**WARNING:** Handle specimens as biohazardous material.

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18–28 °C (64–82 °F), prior to analysis.

##### **Specimen Storage and Stability for CREA: Serum and Plasma<sup>7</sup>**

Storage	Temperature	Stability
Room temperature	18–28 °C (64–82 °F)	≤ 5 days
Refrigerated	2–8 °C (36–46 °F)	≤ 30 days
Frozen	≤ -18 °C (≤ 0 °F)	Indefinite

### Urine

##### *Specimen Collection and Preparation*

- Collect specimens using standard laboratory procedures.<sup>8</sup>
- Keep refrigerated until analysis.

**Note:** For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

##### **Patient Preparation**

No special patient preparation is necessary.

##### **Special Precautions**

Urine specimens must be pretreated prior to processing. Refer to "Specimen Pretreatment" for instructions.

##### *Specimen Handling and Storage*

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18–28 °C (64–82 °F), prior to analysis.

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Specimen Pretreatment

## Specimen Storage and Stability for CREA: Urine<sup>9</sup>

Storage	Temperature	Stability
Room temperature	18–28 °C (64–82 °F)	≤ 3 days
Refrigerated	2–8 °C (36–46 °F)	≤ 5 days
Frozen	≤ -18 °C (≤ 0 °F)	Indefinite

## Specimen Pretreatment

### Urine

#### Predilution

**IMPORTANT:** *If using a VITROS 250/350 or 5,1 FS Chemistry System in On-Analyzer Dilution Mode, do not manually dilute samples for analysis and do not multiply by a dilution factor after analysis. Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure.*

1. Mix 1 part sample with 20 parts of reagent-grade water.
2. Analyze.
3. Multiply the results by 21 to obtain the creatinine concentration in the original urine sample.

## Materials Provided

VITROS Chemistry Products CREA Slides

## Materials Required but Not Provided

- VITROS Chemistry Products Calibrator Kit 1
- Quality control materials, such as VITROS Chemistry Products Performance Verifier I and II for serum and plasma
- VITROS Chemistry Products 7% BSA
- Reagent-grade water
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution of serum and plasma samples)
- VITROS Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water) (for on-analyzer dilution of urine samples)

## Testing Procedure

### Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned workload.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

**IMPORTANT:** *Bring all fluids and samples to room temperature, 18–28 °C (64–82 °F), prior to analysis.*

### Sample Dilution

#### Serum and Plasma

If creatinine concentrations exceed the system's reportable (dynamic) range or if the analyzer displays a DP code (indicating high background density, usually due to an elevated creatine concentration):

#### Manual Sample Dilution

1. Dilute the sample with VITROS 7% BSA.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's creatinine concentration.

#### On-Analyzer Sample Dilution (VITROS 5,1 FS and 250/350 Systems only)

Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure. For VITROS 5,1 FS, use VITROS Chemistry Products FS Diluent Pack 2 for the dilution.

#### Urine

If creatinine concentrations exceed the system's reportable (dynamic) range:

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## VITROS 250/350 and 950 Systems

1. Mix 1 part prediluted sample with 1 part reagent-grade water.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the creatinine concentration in the original sample.

### On-Analyzer Sample Dilution (VITROS 5,1 FS System only)

Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure. Use VITROS Chemistry Products FS Diluent Pack 3 for the dilution.

## Calibration

### Required Calibrators

VITROS Chemistry Products Calibrator Kit 1

**Note:** The same VITROS Calibrator Kit is used to calibrate serum, plasma, and urine creatinine. However, specific supplementary assigned values (SAVs) are applied for each body fluid.

### Calibrator Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Calibrator Kit 1.

### Calibration Procedure

Refer to the operating instructions for your VITROS Chemistry System.

### When to Calibrate

Calibrate:

- When the slide lot number changes.
- When critical system parts are replaced due to service or maintenance.
- When government regulations require.

For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months.

The VITROS CREA test may also need to be calibrated:

- If quality control results are consistently outside acceptable range.
- After certain service procedures have been performed.

For additional information, refer to the operating instructions for your VITROS Chemistry System.

### Calculations

Reflectance from the slide is read at 670 nm at two fixed time points during the incubation period, and the change in reflectance between these two readings is calculated. Once a calibration has been performed for each slide lot, creatinine concentration in unknown samples can be determined using the software-resident two-point rate math model and the change in reflectance calculated for each unknown test slide.

### Validity of a Calibration

Calibration parameters are automatically assessed by the VITROS Chemistry System against a set of quality parameters detailed in the Coefficients and Limits screen (for VITROS 5,1 FS, see the Review Assay Data screen). Failure to meet any of the pre-defined quality parameters results in a failed calibration. The calibration report should be used in conjunction with quality control results to determine the validity of a calibration.

### Reportable (Dynamic) Range

#### Reportable (Dynamic) Range for CREA

	Conventional Units (mg/dL)	SI Units ( $\mu$ mol/L)	Alternate Units (mg/L)
Serum	0.05–14.0	4–1238	0.5–140
Urine	1.2–346.5*	107–30639*	12.0–3465*

\* After multiplying by a dilution factor of 21.

For out-of-range samples, refer to "Sample Dilution."

### Traceability of the Calibration

The values assigned to the VITROS Chemistry Products Calibrator Kit 1 for Creatinine are traceable to a Gas Chromatography Isotope Dilution Mass Spectrometry (GC/IDMS) method<sup>10</sup> and National Institute of Standards and Technology (NIST) SRM<sup>®</sup>914 creatinine standard reference material.

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Quality Control

## Quality Control

### Procedure Recommendations

**WARNING:** *Handle quality control materials as biohazardous material.*

- Choose control levels that check the clinically relevant range.
- Analyze quality control materials in the same manner as patient samples, before or during patient sample processing.
- To verify system performance, analyze control materials:
  - After calibration.
  - According to local regulations or at least once each day that the test is being performed.
  - After specified service procedures are performed. Refer to the operating instructions for your VITROS Chemistry System.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- For general quality control recommendations, refer to *Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline-Third Edition*<sup>11</sup> or other published guidelines.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

### Quality Control Material Selection

**IMPORTANT:** *VITROS Performance Verifiers are recommended for use with the VITROS Chemistry System. Evaluate the performance of other commercial control fluids for compatibility with this test before using for quality control.*

- Controls that are reconstituted with deionized water should perform acceptably.
- Control materials other than VITROS Performance Verifiers may show a difference when compared with other creatinine methods if they:
  - Depart from a true human matrix.
  - Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives.
- Liquid serum and urine controls often contain high creatine levels and may give DP codes.
- Do not use control materials stabilized with ethylene glycol.

#### **Urine**

For urine specimens, use commercially available urine control materials.

**IMPORTANT:** *If using a VITROS 250/350 or 5,1 FS Chemistry System in On-Analyzer Dilution Mode, do not manually dilute samples for analysis and do not multiply by a dilution factor after analysis. Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure.*

### Quality Control Material Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Chemistry Products Performance Verifier I and II or to other manufacturer's product literature.

## Expected Values and Reporting Units

**IMPORTANT:** *If using results to calculate an estimated glomerular filtration rate (eGFR), confirm that you are using the appropriate MDRD (Modification of Diet in Renal Disease) equation.<sup>12</sup>*

### Reference Interval

The serum reference intervals are the central 95% of results from an external study of apparently healthy adults (serum: 180 males and 180 females).

The urine reference intervals are based on a separate external study.<sup>13</sup>

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Limitations of the Procedure

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## Reference Interval for CREA

	Conventional Units	SI Units	Alternate Units
<b>Serum</b>			
<b>Male</b>	0.66–1.25 mg/dL	58–110 µmol/L	6.6–12.5 mg/L
<b>Female</b>	0.52–1.04 mg/dL	46–92 µmol/L	5.2–10.4 mg/L
<b>Urine</b>			
<b>Male</b>	1000–2000 mg/day*	8840–17680 µmol/day**	1000–2000 mg/day***
<b>Female</b>	800–1800 mg/day*	7072–15912 µmol/day**	800–1800 mg/day***

\* Creatinine concentration (mg/dL) x 24-hour volume (dL) = mg/day.

\*\* Creatinine concentration (µmol/L) x 24-hour volume (L) = µmol/day.

\*\*\* Creatinine concentration (mg/L) x 24-hour volume (L) = mg/day.

Each laboratory should confirm the validity of these intervals for the population it serves.

## Reporting Units and Unit Conversion

The VITROS Chemistry System may be programmed to report creatinine results in conventional, SI, and alternate units.

### Reporting Units and Unit Conversion for CREA

Conventional Units	SI Units	Alternate Units
mg/dL	µmol/L (mg/dL x 88.4)	mg/L (mg/dL x 10)

## Limitations of the Procedure

### Known Interferences

#### Serum and Plasma

- **Creatine:** At a creatinine concentration of 1.5 mg/dL (133 µmol/L), creatine greater than 8 mg/dL (707 µmol/L) will be flagged with a DP code (because highly elevated creatine concentrations may cause excessive background density). For unflagged samples, residual bias because of creatine will be less than 0.15 mg/dL (13 µmol/L). At a creatinine concentration of 14 mg/dL (1237 µmol/L), creatine greater than 1 mg/dL (88 µmol/L) will be flagged with a DP code. Residual bias for unflagged samples will be less than 2%. Refer to “Sample Dilution” for dilution instructions.
- **Proline:** Patients receiving hyperalimentation fluids containing proline may show an increase of 0.2 mg/dL (18 µmol/L). Do not collect specimens from intravenous fluid lines contaminated with hyperalimentation fluid.
- **Dobutamine:** Specimens contaminated with dobutamine from intravenous fluid have been reported to show a significant negative bias. A dobutamine concentration of 83 µg/mL caused a decrease of 2.7 mg/dL (239 µmol/L) from an initial creatinine concentration of 4.8 mg/dL (424 µmol/L).<sup>14</sup>
- **Lidocaine:** Patients on long-term lidocaine therapy may show an increase of up to 1.0 mg/dL (88 µmol/L) due to a metabolite of lidocaine, N-ethyl glycine (NEG).<sup>15</sup>

The VITROS CREA Slide method was screened for interfering substances following NCCLS Protocol EP7.<sup>16</sup> The substances listed in the table, when tested at the concentrations indicated, caused the bias shown.

For substances that were tested and did not interfere, refer to “Specificity.”

### Known Interfering Substances for CREA

Interferent*	Interferent Concentration		Creatinine Concentration		Bias	
			Conv. (mg/dL)	SI (µmol/L)	Conv. (mg/dL)	SI (µmol/L)
Dipyron (Metamizol)	40 mg/dL	(1138 µmol/L)	1.0	88	-0.6	-53
Hemoglobin	900 mg/dL	(9 g/L)	1.5	133	-0.1	-9
N-acetylcysteine	90 mg/dL	(5.50 mmol/L)	1.3	115	-0.4	-35

\* It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

### Other Limitations

Certain drugs and clinical conditions are known to alter creatinine concentration *in vivo*. For additional information, refer to one of the published summaries.<sup>17, 18</sup>

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Performance Characteristics

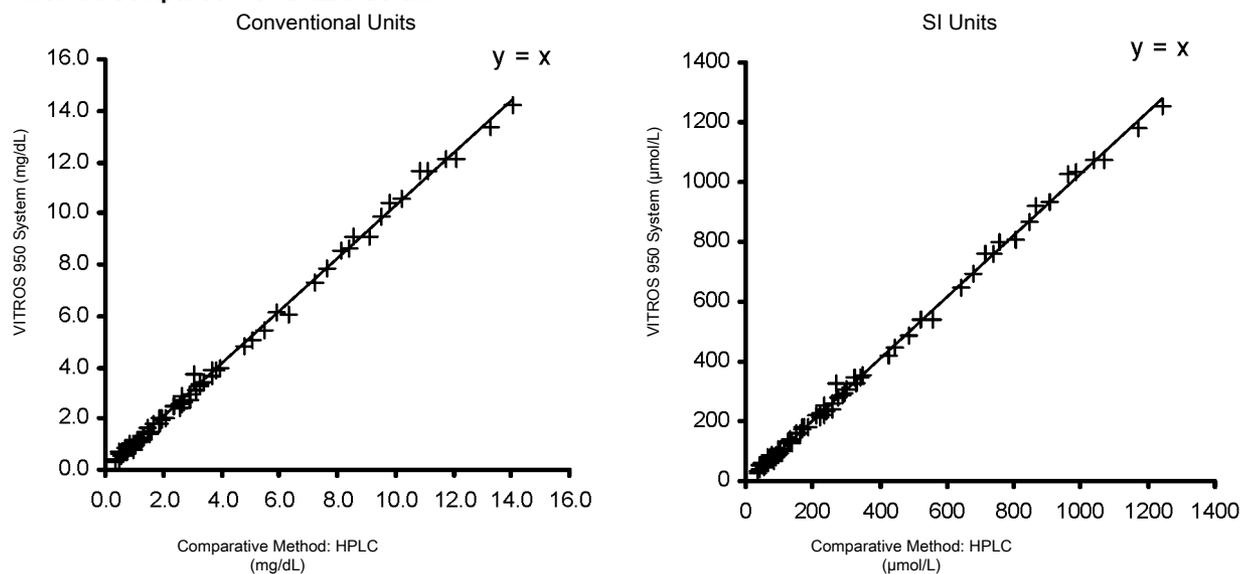
## Performance Characteristics

### Method Comparison

The plots and tables below show the results of a method comparison study for serum samples and for urine samples analyzed on the VITROS 950 Chemistry System, and with the Ortho-Clinical Diagnostics, Inc. comparative method (an HPLC method),<sup>19</sup> which has demonstrated equivalence to the Gas Chromatography Isotope Dilution Mass Spectrometry (GC/IDMS) reference method. Testing followed NCCLS protocol EP9.<sup>20</sup>

The tables also show the results of comparisons of the VITROS 5,1 FS and 250/350 systems with the VITROS 950 System.

### Method Comparison for CREA: Serum



### Method Comparison for CREA: Serum

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (µmol/L)		
				Range of Sample Conc.	Intercept	Sy.x	Range of Sample Conc.	Intercept	Sy.x
<b>950 System vs. Comparative Method*</b>	82	1.03	0.998	0.29–14.18	-0.03	0.16	26–1254	-2.87	14.52
<b>250/350 System vs. 950 System</b>	109	0.98	1.000	0.1–13.3	+0.03	0.07	10–1172	+2.98	6.23
<b>5,1 FS System vs. 950 System</b>	124	1.06	0.998	0.2–13.8	-0.001	0.16	14–1220	-0.09	13.75

\* In accordance with the recommendation by the NKDEP to standardize serum creatinine measurements across IVD manufacturers, the HPLC method has demonstrated equivalence to the IDMS method.

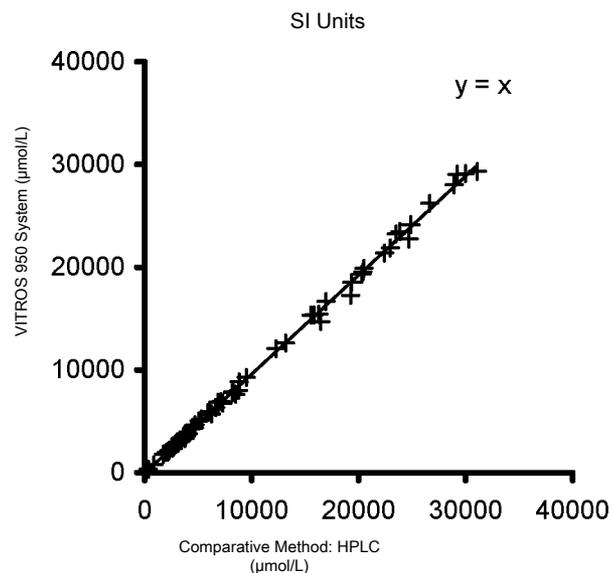
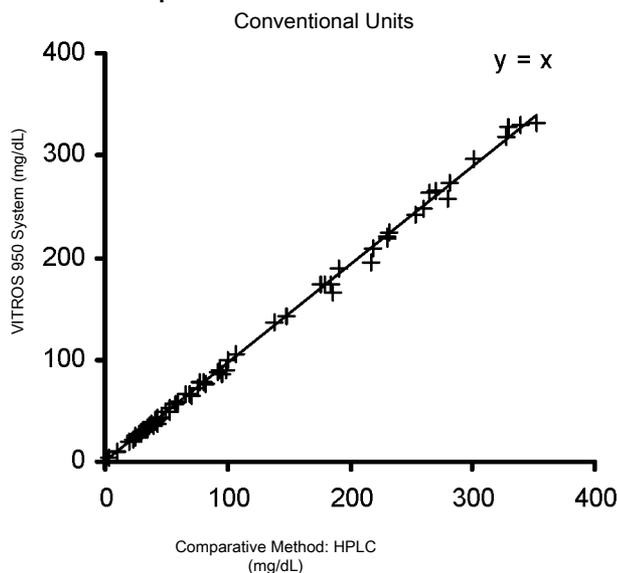
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## Performance Characteristics

## Creatinine for GENs 80 and above

**Method Comparison for CREA: Urine**



**Method Comparison for CREA: Urine**

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (µmol/L)		
				Range of Sample Conc.	Intercept	Sy.x	Range of Sample Conc.	Intercept	Sy.x
<b>950 System vs. Comparative Method</b>	75	0.96	0.999	3.67–331.81	-0.29	3.55	325–29332	-26.00	314.00
<b>250/350 System vs. 950 System</b>	167	0.96	1.000	5.3–320.4	+1.79	1.84	465–28325	+158.59	162.96
<b>5,1 FS System vs. 950 System</b>	167	0.98	1.000	2.9–328.4	+1.19	2.03	257–29028	+105.59	179.09

### Precision

Precision was evaluated with quality control materials on VITROS 250/350, 950 and 5,1 FS Systems following NCCLS Protocol EP5.<sup>21</sup>

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

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Performance Characteristics

## Precision for CREA: Serum

System	Conventional Units (mg/dL)			SI Units (µmol/L)			Within Lab CV% <sup>**</sup>	No. Observ.	No. Days
	Mean Conc.	Within Day SD <sup>*</sup>	Within Lab SD <sup>**</sup>	Mean Conc.	Within Day SD <sup>*</sup>	Within Lab SD <sup>**</sup>			
VITROS 950	0.37	0.010	0.015	33	0.9	1.3	4.1	84	22
	0.94	0.016	0.018	83	1.4	1.6	1.9	84	22
	5.10	0.065	0.077	451	5.7	6.8	1.5	84	22
	13.11	0.122	0.151	1159	10.8	13.3	1.1	84	22
VITROS 250/350	0.37	0.006	0.010	33	0.5	0.9	2.6	88	22
	0.95	0.009	0.013	84	0.8	1.1	1.3	88	22
	5.01	0.049	0.085	443	4.4	7.5	1.7	88	22
	13.05	0.109	0.203	1153	9.6	18.0	1.6	88	22
VITROS 5,1 FS	0.41	0.012	0.020	36	1.0	1.8	4.8	84	22
	0.92	0.015	0.020	82	1.3	1.8	2.1	88	22
	5.46	0.071	0.085	483	6.2	7.5	1.6	88	22
	13.58	0.098	0.133	1200	8.7	11.7	1.0	84	22

<sup>\*</sup> Within Day precision was determined using two runs/day with two to three replications.

<sup>\*\*</sup> Within Lab precision was determined using a single lot of slides and calibrating weekly.

## Precision for CREA: Urine

System	Conventional Units (mg/dL)			SI Units (µmol/L)			Within Lab CV% <sup>**</sup>	No. Observ.	No. Days
	Mean Conc.	Within Day SD <sup>*</sup>	Within Lab SD <sup>**</sup>	Mean Conc.	Within Day SD <sup>*</sup>	Within Lab SD <sup>**</sup>			
VITROS 950	61.5	0.85	1.43	5441	75.2	126	2.3	84	22
	82.8	0.74	1.03	7320	65.2	91	1.2	84	22
	146.6	2.23	2.73	12962	196.8	241	1.9	84	22
	231.9	2.18	2.85	20502	192.5	252	1.2	84	22
VITROS 250/350	56.2	0.71	1.42	4969	63.2	126	2.5	88	22
	79.4	0.61	1.32	7065	54.0	117	1.7	88	22
	131.4	1.81	3.11	11613	159.6	275	2.4	90	22
	219.3	2.23	3.89	19387	197.5	344	1.8	86	22
VITROS 5,1 FS	61.4	1.01	1.40	5424	89.7	124	2.3	88	22
	81.6	0.81	1.14	7209	71.9	101	1.4	88	22
	146.5	2.50	3.02	12951	221.1	267	2.1	88	22
	229.9	2.39	3.19	20328	211.4	282	1.4	88	22

<sup>\*</sup> Within Day precision was determined using two runs/day with two to three replications.

<sup>\*\*</sup> Within Lab precision was determined using a single lot of slides and calibrating weekly.

## Specificity

### Substances That Do Not Interfere

The substances listed in the table were tested with VITROS CREA Slides following NCCLS Protocol EP7<sup>22</sup> and found not to interfere, bias <0.1 mg/dL (<8.8 µmol/L), at the concentration shown.

### Substances That Do Not Interfere With CREA

Compound	Concentration		Compound	Concentration	
Acetoacetate	30 mmol/L	30 mmol/L	Isoniazid	1.5 mg/dL	109 µmol/L
Ampicillin	1.5 mg/dL	43 µmol/L	Limcomycin	1.5 mg/dL	37 µmol/L
Amikacin	1.5 mg/dL	26 µmol/L	Methicillin	1.5 mg/dL	37 µmol/L
Ammonium Chloride	1 mmol/L	1 mmol/L	6-Mercaptopurine	1.5 mg/dL	99 µmol/L
Amphotericin B	1.5 mg/dL	16 µmol/L	Minocycline	1.5 mg/dL	33 µmol/L
Ascorbic Acid	3 mg/dL	170 µmol/L	Nalidixic Acid	1.5 mg/dL	65 µmol/L
Bacitracin	1.5 mg/dL	11 µmol/L	Nafcillin	1.5 mg/dL	34 µmol/L
Bicarbonate	40 mmol/L	40 mmol/L	Neomycin	1.5 mg/dL	24 µmol/L
Bilirubin	20 mg/dL	342 µmol/L	Nitrofurantoin	1.5 mg/dL	63 µmol/L

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Compound	Concentration		Compound	Concentration	
Bleomycin Sulfate	1.5 mg/dL	11 µmol/L	Oxacillin	1.5 mg/dL	37 µmol/L
Carbenicillin	1.5 mg/dL	40 µmol/L	Oxytetracycline	1.5 mg/dL	33 µmol/L
Cefazolin	1.5 mg/dL	33 µmol/L	Penicillin-g	1.5 mg/dL	45 µmol/L
Cephalothin	1.5 mg/dL	38 µmol/L	Phenobarbital	3 mg/dL	129 µmol/L
Cephaloridine	1.5 mg/dL	36 µmol/L	Phenoxyethylpenicillinic acid	1.5 mg/dL	43 µmol/L
Cephaloglycin	1.5 mg/dL	37 µmol/L	pH	6.8	6.8
Cephalexin	1.5 mg/dL	43 µmol/L	pH	8.8	8.8
Cephadrine	1.5 mg/dL	43 µmol/L	Polymyxin B sulfate	1.5 mg/dL	13 µmol/L
Cleocin	1.5 mg/dL	35 µmol/L	Polymyxin E	1.5 mg/dL	13 µmol/L
Cloxacillin	1.5 mg/dL	34 µmol/L	Potassium	8 mEq/L	8 mmol/L
Demeclocycline	1.5 mg/dL	32 µmol/L	Rifampicin	1.5 mg/dL	18 µmol/L
Dextran	1000 mg/dL	250 µmol/L	Spectinomycin	1.5 mg/dL	45 µmol/L
Dicloxacillin	1.5 mg/dL	32 µmol/L	Streptomycin sulfate	1.5 mg/dL	13 µmol/L
Doxycycline	1.5 mg/dL	32 µmol/L	Sulfachloropyridazine	1.5 mg/dL	53 µmol/L
Di-cycloserine	1.5 mg/dL	147 µmol/L	Sulfamethoxypyridazine	1.5 mg/dL	54 µmol/L
Dilantin	2 mg/dL	79 µmol/L	Sulfamethoxazole	1.5 mg/dL	59 µmol/L
Ethambutol	1.5 mg/dL	73 µmol/L	Sulfisoxazole	1.5 mg/dL	56 µmol/L
Ethanol	300 mg/dL	65 mmol/L	Sulfadiazine	1.5 mg/dL	60 µmol/L
Furazolidone	1.5 mg/dL	67 µmol/L	Sulfathiazole	6 mg/dL	235 µmol/L
5-Fluorocytosine	5 mg/dL	387 µmol/L	Tetracycline	1.5 mg/dL	34 µmol/L
Gentamicin	1.5 mg/dL	32 µmol/L	Ticarillin	1.5 mg/dL	39 µmol/L
Glucose	600 mg/dL	33 mmol/L	Tolbutamide	22 mg/dL	814 µmol/L
Glutathione	1 mg/dL	33 µmol/L	Triglycerides	800 mg/dL	9 mmol/L
Hypaque	500 mg/dL	8.2 mmol/L	Vancomycin	1.5 mg/dL	10 µmol/L
Intralipid	800 mg/dL	8 g/L	Urea Nitrogen	100 mg/dL	36 mmol/L
Kanamycin	1.5 mg/dL	31 µmol/L	Uric Acid	15 mg/dL	892 µmol/L

### Urine

The following preservatives have been tested and demonstrated an effect of less than 2% on creatinine results:

- Thymol
- Toluene
- Boric acid
- Glacial acetic acid (0.5 to 1.0 v/v)
- 12N HCl
- NH<sub>4</sub>OH
- Bromide
- Iodide
- 5% NaOH

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# CREA

Creatinine for GENs 80 and above

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Glossary of Symbols

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## Glossary of Symbols

The following symbols may have been used in the labeling of this product.

	Do Not Reuse		Upper Limit of Temperature		This end up
	Use by or Expiration Date (Year-Month-Day)		Lower Limit of Temperature		SI Units
	Lot Number		Temperature Limitation		Conventional Units
	Serial Number		Consult Instructions for Use		Value
	Catalog Number or Product Code		Irritant		Range
	Attention: See Instructions for Use		Harmful		Range of Means
	Manufacturer		Toxic		Midpoint
	Authorized Representative in the European Community		Fragile, Handle with Care		Revised
	Contains Sufficient for "n" Tests		Keep Dry		Supersedes
	<i>In vitro</i> Diagnostic Medical Device		Der Grüne Punkt (the Green Dot). Manu- facturer follows certain packaging material waste disposal management regulations		Estimate within-lab SD

# INSTRUCTIONS FOR USE

# CREA

Revision History

Creatinine for GENs 80 and above

## Revision History

Date of Revision	Version	Description of Technical Changes*
2007-10-22	2.0	<ul style="list-style-type: none"> <li>Sample Dilution: Urine – Corrected data</li> <li>Reference Interval – Updated data for serum</li> </ul>
2007-01-25	1.0	First Release of Document

\* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Obsolete Date



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