

Intended Use

Intended for use as an creatinine standard for standardization or calibration of modified Jaffe or enzymatic creatinine procedures

Summary and Explanation

The creatinine standard is prepared from creatinine in an aqueous solution. The standard provides a concentration level of creatinine within the linearity range of the modified Jaffe or enzymatic creatinine procedure. Stabilizers and preservatives added.

Principle

The standard should be used to calibrate the determination of unknown specimens using a modified Jaffe or enzymatic creatinine assay. Controls should be included to validate the calibration of the assay.

Ingredients

Reactive ingredients: An aqueous solution containing creatinine. Preservatives added. Consult vial label for assigned concentration for the standard.

Precautions: For *in vitro* diagnostic use. Handle with the same precautions used for human samples.

Storage and stability

Store at room temperature, 15-30°C. Stable until expiration date if sealed tightly and stored at 15-30°C.

Preparation

Standard is provided as a ready to use liquid.

Procedure

The standard should be used to standardize instrument or assay following the directions that accompany the instrument and reagent kit used.

Materials provided: Aqueous Creatinine standard 2.50 mg/dl.










Materials not provided: Pointe Scientific modified Jaffe or enzymatic creatinine reagent and controls.

Limitations: Factors that might cause inaccurate results are improper pipetting and inadequate mixing.

Standard Value

The value is 2.50 mg/dl when used with the Pointe Scientific modified Jaffe or enzymatic creatinine procedure.

Symbol Key

 Use by (YYYY-MM)	 Lot and batch code
 Catalog number	 Manufacturer
 <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	 CE mark
 Authorized representative in the European Community	



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