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Role:	Reviewer
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M.S.D.N: 0310805269 - C.T.T.N.H.H. CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM Q. BÌNH THẠNH - T.P. HỒ CHÍ MINH

Trương Thị Tố Hoa
Trưởng phòng Đăng ký,
Đối ngoại và Quản lý Chất lượng

Specification

Product: **Creatinine Jaffé Gen.2 (CREJ2)**

Catalog No. 05401755190

Intended use:
In vitro test for the quantitative determination of creatinine in human serum, plasma and urine on the cobas c 111 system.

Test principle:
This kinetic colorimetric assay is based on the Jaffé method. In alkaline solution, creatinine forms a yellow-orange complex with picrate.
The rate of dye formation is proportional to the creatinine concentration in the specimen.
The assay uses “rate-blanking” to minimize interference by bilirubin.
To correct for non-specific reaction caused by serum/plasma pseudo-creatinine chromogens, including proteins and ketones, the results for serum or plasma are corrected by -18 µmol/L (-0.2 mg/dL).

Creatinine + picric acid $\xrightarrow{\text{AlkalinepH}}$ yellow-orange complex

Roche Diagnostics GmbH
Roche Diagnostics Global Operations
Quality Control Mannheim

D-68305 Mannheim
Phone: +49-621-759-0
Fax: +49-621-759-2890

1. Reagents-working solutions:

1.1 Alkaline buffer solution (R1):

1.1.1 pH-value (25 °C): ≥ 13.5

1.2 Picric acid solution (R2):

1.2.1 pH-value (25 °C): 6.00 - 7.00

2. Performance test:

2.1 Recovery on cobas c 111 analyzer:

PreciControl ClinChem Multi 1 (Cat. No. 05947626190): 90 - 110 %

PreciControl ClinChem Multi 2 (Cat. No. 05947774190): 90 - 110 %

Also required:
Calibrator f.a.s. (Cat. No. 10759350190)