

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k073080

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for general chemistry analytes (see device description below)

D. Type of Test:

N/A

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Quest Diagnostics Serum Chemistry Control

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product code:
JJY, Multi-Analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
Quest Diagnostics Serum Chemistry Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
2. Indication(s) for use:
See intended use section above.
3. Special conditions for use statement(s):

For *in vitro* diagnostic use; for prescription use

4. Special instrument requirements:
Olympus AU5400

I. Device Description:

Quest Diagnostics Serum Chemistry Controls are provided as three levels of control materials. They are prepared from human serum to which purified biochemical materials (tissue extracts of human and animal origin), chemicals, preservatives and stabilizers have been added.

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

The analyte constituents are as follows:

– Alanine Aminotransferase (ALT /SGPT)	– Gamma-Glutamyltransferase (GGT)
– Albumin	– Glucose
– Alkaline Phosphatase (ALP)	– Iron
– Amylase	– Iron-Binding Capacity, Unsaturated (UIBC)
– Aspartate Aminotransferase (AST/SGOT)	– Lactate Dehydrogenase (LDH)
– Bilirubin, Direct	– Lipase
– Bilirubin, Total	– Magnesium
– Blood Urea Nitrogen	– Phosphorous
– Calcium	– Potassium
– Chloride	– Sodium
– Cholesterol	– Thyroxine (T4)
– Cholesterol, HDL	– T3 Uptake
– CO2	– Total Protein
– Creatine Kinase (CK)	– Triglycerides
– Creatinine	– Uric Acid
– Cholesterol, LDL	

J. Substantial Equivalence Information:

1. Predicate device name(s):
Quest Diagnostics Serum Chemistry Control
2. Predicate 510(k) number(s):
k033387
3. Comparison with predicate:

Quest Diagnostics Serum Chemistry Control claims substantial equivalence to the Quest Diagnostics Serum Chemistry Control currently in commercial distribution. The new Quest Diagnostics Serum Chemistry Control contains the claims for the same analytes as the predicate device, with the addition of new claims for LDL-cholesterol. The predicate claimed ranges for analytes tested on both the Olympus AU5200 and AU5400. This device claims ranges for analytes tested on the Olympus AU5400 only.

K. Standard/Guidance Document Referenced (if applicable):

None were reference.

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

No traceability was provided.

The ranges were established as follows, limits for mean values (at least 20 replicates) \pm 3SDs of the mean or 25% of allowable total error (ATE). The mean values printed in the package were derived from replicate measurements from various Quest Laboratories using the Olympus AU5400 and are lot specific. The labeling indicates that individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of the control material. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. The sponsor recommends in the labeling that each laboratory establish its own means and acceptable ranges and use those provided in the labeling only as guides.

Stability studies have been performed to determine the open vial stability and shelf life for the Quest Diagnostics Serum Chemistry Control. Product claims are as follows: open vial: 30 days when stored tightly capped at 2-8°C; alternate Stability (Closed vial): 6 months when stored at -10 to -20°C; and shelf Life: Two years when stored at -20 to -70°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

