

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

A. 510(k) Number:

k090940

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for newborn screening assays screening for deficiencies in Biotinidase and Galactose-1-phosphate Uridyltransferase (GALT) enzyme activity

D. Type of Test:

Quality control materials

E. Applicant:

Astoria-Pacific, Inc.

F. Proprietary and Established Names:

SPOTCHECK Blood Spot Controls

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1660, Quality control material
2. Classification:
Class I, reserved
3. Product code:
JJT, Enzyme controls
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
SPOTCHECK Blood Spot Controls are used for monitoring assay performance during *in vitro* diagnostic newborn screening for deficient Galactose-1-phosphate Uridyltransferase (GALT) and/or Biotinidase enzyme activity. Enzyme response quantitation is provided in the product insert.
2. Indication(s) for use:
See intended use(s) above.

3. Special conditions for use statement(s):
For prescription use only.

4. Special instrument requirements:
Astoria-Pacific SPOTCHECK Analyzer

I. Device Description:

The controls are prepared with mixtures of human serum and human red blood cells, and adjusted to approximately 55% hematocrit. Enzyme activity in the Deficient Control is decreased by heating. Enzyme activity in the Normal Control is supported by the addition of dithioerythritol (DTE). The mixtures are spotted on Whatman 903A filter paper and allowed to air dry at room temperature.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bio-Rad Laboratories Quantase Neonatal GALT control set

2. Predicate K number(s):
k990827

3. Comparison with predicate:

Similarities		
Item	Predicate Device (k990827)	Proposed Device
Matrix	Dried blood spots	Same
Intended use	Both devices intend to establish performance of a control below the assay cutoff (deficient) and above the cutoff (within normal limits).	Same

Differences		
Item	Predicate Device (k990827)	Proposed Device
Analytes	Galactose-1-phosphate Uridyltransferase (GALT)	Galactose-1-phosphate Uridyltransferase (GALT) and Biotinidase

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

- Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

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):*

Value assignment: Control lots are individually tested using FDA-cleared SPOTCHECK Biotinidase and Uridyl Transferase 50-Hour Reagent Kits to determine the response of each analyte (enzyme) present. The controls are analyzed internally on multiple SPOTCHECK instruments. The Normal Control spots on each card in a series of selected cards are randomly punched until each card has been sampled 10 times. Similarly, Deficient Control spots are punched until each card in a series has been sampled 2 times. From each lot analysis, the mean activity, standard deviation with confidence intervals, and coefficient of variation are calculated.

The target values are:

- The Normal Control mean activity must be in the range of 30 – 60 ERU for the biotinidase assay and > 150 μm NADH for the GALT assay.
- The Deficient Control mean activity must be in the range of 0 – 6 ERU for the biotinidase assay and 0 – 30 μm NADH for the GALT assay.

Inter and intra-card homogeneity is also evaluated for each new lot.

Stability: Recommended storage conditions for the Blood Spot Controls are < -10°C and desiccated. Stored in this manner, the controls are stable for a minimum of 2 years from the manufacture date. The stability has been determined using real-time stability studies. The stability study protocol and the acceptance criteria have been reviewed and found to be acceptable.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

