

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

**A. 510(k) Number:** k041666

**B. Purpose of Submission:** Premarket Notification Abbreviated [510(k)] of intention to manufacture and market the DC-Acetaminophen/Salicylate Controls.

**C. Analyte:** Acetaminophen and salicylate

**D. Type of Test:** NA

**E. Applicant:** Diagnostic Chemicals Limited

**F. Proprietary and Established Names:**  
DC Aceta/Sal Control Set, Cat. Nos. SE-008/SE-010

**G. Regulatory Information:**

1. Regulation section: 21 CFR §862.3280 – clinical toxicology control material
2. Classification: Class I
3. Product Code: DIF
4. Panel: 91

**H. Intended Use:**

1. Intended use(s):

The intended use of the DC-Aceta/Sal is for *in vitro* diagnostic use in quality control procedures to monitor the accuracy and precision of manual and automated acetaminophen and salicylate assays.

2. Indication(s) for use:

The DC Aceta/Sal Control, Cat. Nos. SE-008/SE-010 is intended for *in vitro* use in quality control procedures to monitor the accuracy and precision of manual and automated acetaminophen and salicylate assays.

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

4. Special instrument Requirements: The intended instruments are stated in the package insert.

**I. Device Description:** The DC-Aceta/Sal is a lyophilized preparation of bovine albumin, acetaminophen and salicylate. It is presented in a Level 1 or Level 2 kit format with assayed values published for each lot. Each kit is a cardboard box containing 6 x 3 mL brown serum vials with rubber stoppers and plastic/aluminum seals, appropriate labels and a product insert.

The level one assayed control is Catalog Number SE-008 and the acetaminophen and salicylate values are below the toxic concentration. The level two assayed control is Catalog Number SE-010 and the acetaminophen and salicylate values are at or near the toxic concentration.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):           Lymphocheck Immunoassay Plus Control
3. Predicate k number(s):           k981532
4. Comparison with predicate:

ATTRIBUTE	ACETA/SAL	LYPHOCHEK
Size	6x3 mL	12x5 mL
Format	Lyophilized	Lyophilized
Intended Use	To monitor accuracy & precision of assays	To monitor precision of assays
Reconstitution	Add 3 mL deionized or distilled water	Add 5 mL deionized or distilled water
Source of Base	Bovine Serum	Human Serum
Stability	7 days, after reconstitution at 2 – 8 °C	7 days, after reconstitution at 2 – 8 °C
Storage Temperature	2 – 8 °C	2 – 8 °C
Acetaminophen	Yes	Yes
Salicylate	Yes	Yes
Value Assignment	Lot Specific	Lot Specific
Range of Values	Level 1 and 2	Level 1, 2, and 3

**K. Standard/Guidance Document Referenced (if applicable):**  
None referenced

**L. Test Principle:** NA

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. *Precision/Reproducibility:* NA

*b. Linearity/assay reportable range: NA*

*c. Traceability (controls, calibrators, or method):*

The constituents of DC Aceta/Sal are the drug compounds acetaminophen and salicylate. These are purchased as bulk chemicals from pre-approved vendors. Values are assigned using 20 vials of each control and the appropriate Diagnostic Chemicals Limited reagent on two different types of analyzers. The value assignment for Acetaminophen is obtained by averaging values from the two different assay methodologies. The value assignment for Salicylate is obtained from a single assay methodology.

Open vial stability of the DC Aceta/Sal controls was assessed at day 1 and 7 on control stored at normal storage temperature and at accelerated temperature. The assay reagents were considered stable to 14 days, if there was  $\pm 10\%$  deviation from day 0 results.

Long term real time stability studies were performed and run one month past stated stability.

*c. Detection limit: NA*

*d. Analytical specificity: NA*

*e. Assay cut-off: NA*

2. Comparison studies:

*a. Method comparison with predicate device: NA*

*b. Matrix comparison: NA*

3. Clinical studies:

*a. Clinical sensitivity: NA*

*b. Clinical specificity: NA*

*c. Other clinical supportive data (when a and b are not applicable): NA*

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

**N. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.