

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

A. 510(k) Number:

K051706

B. Purpose for Submission:

To obtain clearance for the iQ[®] Body Fluids Control for Iris Diagnostics.

C. Measurand:

Body fluid red blood cells and nucleated cell counts

D. Type of Test:

Control for evaluating body fluid cell counts

E. Applicant:

Streck Laboratories

F. Proprietary and Established Names:

iQ[®] Body Fluids Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

JPk

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

iQ[®] Body Fluids Controls are intended for use on iQ[®] Series analyzers, with the optional iQ[®] Body Fluids Module installed, as a control for evaluating body fluid RBC and nucleated cell counts. The device will consist of two levels of red blood cells and nucleated cells.

2. Indication(s) for use:

iQ[®] Body Fluids Controls are intended for use on iQ[®] Series analyzers, with the optional iQ[®] Body Fluids Module installed, as a control for evaluating body fluid RBC and nucleated cell counts. The device will consist of two levels of red blood cells and nucleated cells.

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

iQ[®] Body Fluids Control is a stabilized suspension of human red blood cells and simulated white blood cells in a solution containing biological salts and anti-microbial preservatives. The product is packaged in glass vials containing 8 ml. The closures are polypropylene screw caps with polyethylene liners. Four vials are included in a set. Two vials are level 1 with a low cell count and the other two vials are level 2 with a higher concentration of cells. The vials are further packaged in a six (6) well vacuum formed “clam-shell” container with the package insert / assay sheet. The product must be stored at 2 – 10° C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cell-Chex

2. Predicate 510(k) number(s):

K000076

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Reagent components	Assayed mixture of red and white blood cells set at specific concentrations	Same
Stability	30-day open vial stability	Same

Differences		
Item	Device	Predicate
Instrumentation	Iris Diagnostics' iQ [®] Body Fluids Module	Manual diagnostic methods
Stability	40-day closed vial stability	6-month closed vial stability

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

L. Test Principle:

The iQ[®] Body Fluids Controls were designed to provide a cell mixture that would be useful as positive controls for the Iris Diagnostics' iQ[®] Body Fluids Module. The iQ[®] Body Fluids Module is an in-vitro diagnostic device used by a competent human observer to examine and count red blood cells and nucleated cells in cerebrospinal fluid and serous fluids. A trained technician uses iQ[®] Body Fluids Controls to verify that he or she can count red blood cells and nucleated cells accurately with the iQ[®] Body Fluids Module. When handled like a patient sample, iQ[®] Body Fluids Controls will provide RBC and nucleated cell counts within the expected ranges indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility studies were performed on three lots of each level of iQ[®] Body Fluids Controls. Each value is calculated from 10 consecutive replicates of each level for each pilot lot (a total of 10 data points per level). Repeat testing was conducted at an offsite location using one pilot lot and one patient sample. The mean, SD and % CV were calculated for the data.

b. Linearity/assay reportable range:

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

Open Vial Stability:

Three pilot lots of reagent were set up to verify performance throughout the 30-day open vial dating. On specified days, during a 30-day period, analyses were conducted on the iQ[®] 200 analyzer (13 times, approximately 3 runs per week) from a single vial per level. Reagent vials were returned to refrigerated storage between analysis periods. All lots performed as expected, with parameter recovery within the established assay ranges.

Closed Vial Stability:

Three lots of reagent were set up to verify performance throughout the 40-day expiration dating. On specified days, during a 40-day period, analysis was conducted on the iQ[®] 200 analyzer. Each vial was analyzed three times in succession (one run per week for 3 to 4 weeks for each vial). Reagent vials were returned to refrigerated storage between analysis periods. The data demonstrated no significant trends and consistent recovery of values within the indicated assay range.

iQ[®] Body Fluids Controls are stable through the expiration date when stored at 2 – 10° C. After opening, iQ[®] Body Fluids Controls are stable throughout the open-vial dating, as indicated on the assay sheet when store at 2 – 10° C.

- d. Detection limit:*
- e. Analytical specificity:*
- f. Assay cut-off:*
- 2. Comparison studies:
 - a. Method comparison with predicate device:*
 - b. Matrix comparison:*
- 3. Clinical studies:
 - a. Clinical Sensitivity:*
 - b. Clinical specificity:*
 - c. Other clinical supportive data (when a. and b. are not applicable):

Alternate Site Testing:

Product samples were provided to an alternate site location at UCLA in Los

Angeles, CA. The two levels performed within the assay range.

4. Clinical cut-off:
5. Expected values/Reference range:

The assigned values for red blood cells and nucleated cells were determined by replicate analysis of iQ[®] Body Fluids Controls on iQ[®] 200 Series Analyzers. The mean and expected ranges for both levels of each lot are included in the package insert. The ranges were calculated using all of the data for 40 days from each lot and multiplying the % CV by 2.5. The ranges were set at a minimum of $\pm 20\%$ or, if greater, rounded to the next higher hundred value, i.e. 437 rounded to 500.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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