

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

A. 510(k) Number:

k052148

B. Purpose for Submission:

Clearance of new calibrator material for total iron-binding capacity

C. Measurand:

Not applicable

D. Type of Test:

Calibrator material

E. Applicant:

Reference Diagnostics, Inc.

F. Proprietary and Established Names:

Direct TIBC Calibrator Set

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1150, Calibrator
2. Classification:
Class II
3. Product code:
JIT, Calibrator, Secondary
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The RDI Direct TIBC Calibrator Set is intended for medical purposes for use with the RDI Direct TIBC Kit to establish points of reference that are used in the quantitative determination of Total Iron-Binding Capacity (TIBC) in human serum.

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

Automated chemistry analyzer systems specified in the package insert.

I. Device Description:

The RDI Direct TIBC Calibrator Set is a bi-level human serum based lyophilized product that contains nonreactive stabilizers and additives. The low calibrator pool is manufactured by immunoaffinity removal of transferrin using anti-human transferrin antibody immobilized on agarose beads. The high calibrator pool is manufactured by direct addition of purified human transferrin to a commercially marketed high calibrator serum pool.

All human source material was tested and found non-reactive for HBsAg, HCV, and HIV-1/2 by an FDA-approved method.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Reference Diagnostics Direct TIBC Calibrator

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

k000783

3. Comparison with predicate:

| Similarities | | |
|--------------------------|-------------|-----------|
| Characteristics | Device | Predicate |
| Source | Human serum | Same |
| Physical Characteristics | Lyophilized | Same |

| Differences | | |
|-----------------|-------------------------------|-------------------------|
| Characteristics | Device | Predicate |
| Fill Volume | 1 mL | 5 mL |
| Levels | Two | One |
| Assigned Values | Approximately 100 & 650 µg/dL | Approximately 350 µg/dL |

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

None referenced

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):*

The human serum is purchased from a commercial source. The low calibrator pool is prepared by immunoaffinity removal of transferrin using anti-human transferrin antibody immobilized on agarose beads. The high calibrator pool is prepared by direct addition of purified human transferrin to a commercially marketed high calibrator serum pool. The suppliers for the human serum, the anti-human transferrin antibody and the purified human transferrin provide certificates of analysis for their products.

The values were assigned by analyzing multiple replicates of three lots of the calibrator, prior to lyophilization, using the RDI Magnetic TIBC method in conjunction with a commercially marketed serum iron kit. In addition, correlation studies were performed on sixty-three patient specimens to validate the calibrator assignment.

The sponsor performed studies to verify the following stability claims for the RDI Direct TIBC Calibrator Set.

| Stability | Unopened | Reconstituted |
|------------------|--------------------------------|-------------------------------|
| Lyophilized | 12 months when stored at 2-8°C | 10 days when stored at 2-8°C: |

The results of the accelerated stability studies support the sponsor's claim of a 12 month shelf life when the Direct TIBC Calibrator Set is stored at 2-8° C.

The results of real time studies support the sponsor's claim that the reconstituted Direct TIBC Calibrator Set is stable for 10 days when stored at 2-8° C.

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

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

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

O. Conclusion:

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