

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

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

k080607

**B. Purpose for Submission:**

$\alpha$  1-Acid glycoprotein has been added as a constituent to the previously cleared multi-analyte Roche Calibrator for Automated Systems (C.f.a.s.) Proteins.

**C. Measurand:**

Calibrator materials for analytes are listed in section J. 3. below.

**D. Type of Test:**

Not applicable

**E. Applicant:**

Roche Diagnostics Corporation

**F. Proprietary and Established Names:**

Calibrator for Automated Systems (C.f.a.s.) Proteins

**G. Regulatory Information:**

1. Regulation section:

21 § 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

**H. Intended Use:**

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

The Calibrator for automated systems (C.f.a.s.) Proteins is for use in the calibration of the quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with the Roche automated chemistry systems listed in the package insert

**I. Device Description:**

Calibrator for Automated systems (C.f.a.s.) Proteins is a liquid ready-to-use calibrator for use in the calibration of quantitative clinical chemistry assays. The concentrations of the analytes are lot specific and are indicated in the calibrator labeling. C.f.a.s. Proteins is specified for use with Roche system reagents.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Calibrator for Automated Systems (C.f.a.s.) Proteins

2. Predicate K number(s):

k011226

3. Comparison with predicate:

| <b>Similarities</b> |   |   |
|---------------------|---|---|
| Item                | Device  | Predicate   |
| Intended Use        | For use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers. | .For use in the calibration of quantitative Roche immunoturbidimetric methods on clinical chemistry analyzers   |
| Format              | Same  | Pooled human sera with constituents added as required to obtain desired component levels.   |
| Levels              | Same  | Single Level  |
| Reagent Composition | Same  | Liquid ready-to-use   |
| Matrix              | Same  | Human serum with chemical and biological additives.   |
| Traceability        | Same  | Traceability of the target values is given in the respective instructions for use of the system reagents.   |
| Value Assignment    | Same  | Traceable through Master Lot to standards or reference methods.   |
| Stability           | Same  | <ul style="list-style-type: none"> <li>• Unopened: Stable at 2-8°C until expiration date.</li> <li>• Opened: Stable for 1 month at 2-8°C, with exceptions noted in labeling.</li> </ul> |

| <b>Differences</b>                    |   |  |
|---------------------------------------|---|--|
| Item                                  | Device  | Predicate  |
| Standardization of C4, IgA-2, and C3c | Standardization path modified to adjust the set point of the master calibrator according to recovery of CRM 470 material. | The standardization path used a method comparison of samples run against the C.f.a.s. Master Lot calibration and those same samples analyzed using CRM 470. Results were compared and set points |

| <b>Differences</b>               |   |  |
|----------------------------------|---|--|
| <b>Item</b>                      | <b>Device</b>   | <b>Predicate</b>   |
|                                  |   | for the Master Lot were adjusted to those of CRM 470.                                    |
| Constituent Concentration        | Tolerance range of Ferritin and CRP concentrations were increased.  | Set point below measuring range requiring dilution of high samples.                      |
| Constituents of the calibrators. | Anti-Streptolysin O and Ceruloplasmin are still present in the device, but are no longer used in calibration. Alpha-1 acid glycoprotein is a new constituent. | ASO and Ceruloplasmin were calibrated using the predicate. No Alpha-1 acid glycoprotein. |

#### **Constituent Analytes**

| <b>C.f.a.s. Proteins</b>              | <b>C.f.a.s. Proteins (Predicate Device)</b> |
|---------------------------------------|---|
| $\alpha$ 1-antitrypsin                | $\alpha$ 1-antitrypsin                      |
| Included but no longer value assigned | ASLO  |
| C3c                                   | C3c   |
| C4                                    | C4  |
| Included but no longer value assigned | Ceruloplasmin                               |
| C-Reactive Protein                    | C-Reactive Protein                          |
| Haptoglobin                           | Haptoglobin                                 |
| No longer a constituent               | Prealbumin                                  |
| Transferrin                           | Transferrin                                 |
| Ferritin                              | Ferritin                                    |
| IgG                                   | IgG   |
| IgA                                   | IgA   |
| IgM                                   | IgM   |
| Alpha 1-Acid glycoprotein             | -   |

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

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

#### **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):*

Traceability

| Control or Calibrator        | Standard for Traceability                            |
|------------------------------|--|
| $\alpha$ 1-Acid Glycoprotein | Protein reference preparation ERM® - DA470 (CRM 470) |

Value Assignment

The value assignment takes place in an internal laboratory on several analyzers. Each analyzer runs 3-4 independent series. An independent series includes full calibration using a new calibrator vial and sample vial. After verifying the data for the samples are within tolerance, the mean is used as set point.

Stability

Three different lots were tested for shelf-life stability in real time, and simulated shipping and open bottle stability testing. The data are measured in 2-fold determinations. The percent recovery is calculated based on the assigned value. The acceptance criterion is  $\pm 10\%$  of the assigned value.  $\alpha$ 1-Acid Glycoprotein met the stability criterion of  $\pm 10\%$  of the assigned value for all of the conditions in the protocol.

Real Time Stability testing- shelf life: The C.f.a.s. Proteins is stored at +2 to +8°C. Recovery studies are performed on freshly opened bottles after manufacturing, 7 months, 13 months, 19 months, and 25 months. Results are compared to the assigned values and acceptance criteria are  $\pm 10\%$ .

Stress Testing and Open Bottle Stability Testing: After real time stability testing, simulated shipping and open bottle stability are tested. Protein recovery is compared to the reference material (fresh C.f.a.s. Proteins) up to 25 months. Results are compared to the assigned values and acceptance criteria are  $\pm 10\%$ .

The stability data provided verifies that C.f.a.s. Proteins is stable for a shelf life claim of 24 months.

*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.