

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

A. 510(k) Number: k042625

B. Purpose for Submission: Notification of intent to manufacture and market the device: QuikRead CRP Verification Set

C. Analyte: CRP

D. Type of Test: N/A

E. Applicant: Orion Diagnostica

F. Proprietary and Established Names: Proprietary - Orion Diagnostica QuikRead CRP Verification Set **Established** – Quality Control Material

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1660 Quality control material (assayed and unassayed)
2. Classification: Class I
3. Product Code: JJY
4. Panel: 75

H. Intended Use:

1. Intended use(s): The Orion Diagnostica QuikRead CRP Verification Set is intended for verification of calibration and method validation for the QuikRead CRP System.
2. Indication(s) for use: The Orion Diagnostica QuikRead CRP Verification Set is intended for verification of calibration and method validation for the QuikRead CRP System.
3. Special condition for use statement(s): For prescription use only
4. Special instrument Requirements: N/A

I. Device Description: The Orion Diagnostica QuikRead CRP Verification Set contains three controls with different levels of CRP. The controls are human based materials. Each human donor unit and collected human pleural fluid, has been tested by an FDA approved method and found to be non Reactive

for HIV-1 & 2 Antibody, Serologic Test for Syphilis and Hepatitis Surface B antigen.

J. Substantial Equivalence Information:

1. Predicate device name(s): Orion QuikRead CRP Control Set
2. Predicate K number(s): k042442
3. Comparison with predicate:

Similarities		
Item	Orion Diagnostica QuikRead CRP Verification Set	Orion Diagnostica QuikRead CRP Control Set
Intended use	Orion Diagnostica QuikRead CRP Verification Set is intended for verification of calibration and method validation of the QuikRead CRP System. For <i>in vitro</i> diagnostic use.	QuikRead CRP Control Set is intended for quality control of the QuikRead CRP assay by the QuikRead 101 Instrument. For <i>in vitro</i> diagnostic use.
Levels	3 levels covering the whole measurement range (low, medium and high) to support the implementation of CLIA regulations (method validation and verification of calibration). Levels are appr. 5, 90, and 180 mg/l. The values have been derived from replicate analyses on the QuikRead system and are lot specific. Expected values are printed on the vial labels.	2 levels for daily quality control. Levels are appr. 50 mg/l and 120 mg/l. The values have been derived from replicate analyses on the QuikRead system and are lot specific. Expected values are printed on the vial labels.
Matrix	Human Serum	Human Serum
Form	Liquid, ready to use	Liquid, ready to use
Way of use	Use in the same way as unknown whole blood specimen would be used, following the instructions for the QuikRead CRP test procedure.	Use in the same way as unknown whole blood specimen would be used, following the instructions for the QuikRead CRP test procedure.
Packaging	1 ml of each level	1 ml of each level
Stability	24 months at 2-8 °C	36 months at 2-8 °C

K. Standard/Guidance Document Referenced (if applicable): Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material – FOD# 2231; NCCLS EP5-A Vol 19 Nov 2, 1999 Evaluation of a Precision Performance of Clinical Chemistry Devices.

L. Test Principle: N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:* N/A

b. *Linearity/assay reportable range:* N/A

c. *Traceability (controls, calibrators, or method):* The Orion Diagnostica QuikRead CRP Verification Set is derived from Normal Human Serum that has been lipid stripped and Human C-Reactive Protein from human pleural fluid, certified by Scipac. Normal human serum is used as a diluent with the Scipac CRP protein to prepare control stock. CRP control is then prepared by diluting control stock with normal human serum that has been lipid stripped. Quality Control on bulk solutions. Assayed values are then printed on the control bottle label.

Stability testing of the CRP control was performed at three levels (7, 102, and 151 mg/l) for 0 – 25 months stored at 2 - 8 °C. Absorbance values were stable throughout the testing time indicating an unopened shelf life of 24 months.

Stability testing of opened CRP control stored at 2 - 8 °C at three levels (7, 102, and 151 mg/l) for 14 days. Smaller amounts of sample were used as opposed to normal clinical testing. As a result values are lower than expected. The CRP expected concentrations were within the target limit indicating an open vial stability of 14 days.

d. *Detection limit:* N/A

e. *Analytical specificity:* N/A

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:* N/A

b. *Matrix comparison:* N/A

3. Clinical studies:
 - a. *Clinical sensitivity*: N/A
 - b. *Clinical specificity*: N/A
 - c. *Other clinical supportive data (when a and b are not applicable)*: N/A
4. Clinical cut-off: N/A
5. Expected values/Reference range: N/A

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.