

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

A. 510(k) Number:

K031607

B. Analyte:

C-Reactive Protein (CRP)

C. Type of Test:

Quantitative, Immunoturbidimetric

D. Applicant:

Orion Diagnostica

E. Proprietary and Established Names:

Orion Diagnostica QuikRead® CRP

F. Regulatory Information:

1. Regulation section:
866.5270 C-Reactive Protein Immunological Test System
2. Classification:
Class II
3. Product Code:
DCK
4. Panel:
Immunology

G. Intended Use:

1. Indication(s) for use:
Orion Diagnostica QuikRead® CRP is a quantitative assay of CRP (C-Reactive Protein) in whole blood, or plasma, using the QuikRead® 101 Instrument. Measurement of CRP helps to evaluate the acute inflammatory processes induced by infectious microbial agents or non-infectious inflammatory stimuli.

Quikread CRP Control is intended for quality control of the QuikRead CRP assay by the QuikRead 101 Instrument.
For *in vitro* diagnostic use.

2. Special condition for use statement(s):
3. Special instrument Requirements:
The QuikRead® 101 instrument is a photometer capable of producing quantitative results and is used with the QuikRead® CRP kit.

H. Device Description

The QuikRead CRP System consists of the QuikRead 101 Instrument, QuikRead dispenser, QuikRead CRP kit and QuikRead CRP control. The QuikRead CRP Control is recommended for quality control but is supplied separately. Sample is added to the buffer. The blood cells in whole blood sample are hemolyzed. The assay is performed in the same cuvette. The reagents are precalibrated, and the calibration curve, which is lot specific, is coded onto a magnetic card provided with each kit.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Tina-quant® CRP
2. Predicate K number(s):
K930621
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Principle	Immunturbidimetric	Same
Sample Type	Plasma and whole blood samples	Serum or plasma samples
Calibration	Calibrators traceable to CRM 470	Same
Usability	Use with QuikRead 101 instrument	Use with automated clinical chemistry analyzer
Differences		
Item	Device	Predicate
Calibration	Reagents are precalibrated. The lot-specific calibration curve is coded onto a magnetic card provided with each kit	Analyzer-specific calibration needed with Preciseset Serum Proteins with every reagent lot change
Reportable range	5 to 180 mg/L	3 to approx. 250 mg/L
Antigen excess	High dose effect: >600 mg/L	High dose effect: > 500 mg/L

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

NCCLS EP-6 Vol.6, No. 18, Evaluation of the Linearity of Quantitative Analytical Methods

NCCLS EP5-A Vol. 19 No.2, 1999; Evaluation of Precision Performance of Clinical Chemistry Devices

K. Test Principle:

The Orion Diagnostica Quikread® CRP is an immunoturbidimetric test based on microparticles coated with anti-human CRP F(ab')₂ fragments. The CRP present in the sample reacts with the microparticles, and the resultant change in the turbidity of the solution is measured by the Quikread 101 Instrument.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Inter-Assay precision

Three patient samples with different levels of CRP were used. Twenty measurements were done during five days. Two parallel runs were performed twice a day.

Sample	Plasma (%CV)	Whole Blood (%CV)
low pool	7.7	13.9
medium pool	5.2	2.4
high pool	6.7	4.4

Inter-assay precision around the cut-off range (<5.0):

Specification for SD = <3.0

Plasma mean conc. 7.8 (SD) = 1.16

Blood mean conc. 5.3 (SD) =1.02

Intra-Assay Precision

Three patient samples with different levels of CRP were used. For the calculations, 10 parallel measurements were done.

Sample	Plasma (%CV)	Whole Blood (%CV)
Low	6.9	14.6
Medium	4.3	5.4
High	3.3	2.4

b. *Linearity/assay reportable range:*

The linearity study was performed using two patient samples having high CRP values. The dilutions were performed in steps of 20%

using 0.9% NaCl solutions as diluent. Four parallel measurements were done. The measured and expected values were compared and recovery expressed as percentage. This study conformed to NCCLS EP6.

The recoveries ranged from 98-120%.

Measurement range is 5-180 mg/L.

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

QuikRead CRP test is standardized according to the BCR/CAP/IFCC reference material CRM 470.

d. Detection limit:

less than 3.5 mg/L

e. Analytical specificity:

No interference found with:

400 umol/l (234 mg/l) Bilirubin

200 umol/l (35 mg/l) Vitamin C

10 mmol/l (8.8 mg/l) triglycerides

f. Assay cut-off:

less than 5 mg/L

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison was made on two different sites using two instruments.

In Orion Diagnostica, the Hitachi Analyzer 911 was used and in Jorvi Hospital, Hitachi 917. In Tina-quant CRP test; a stock calibrator is used for making dilutions for standard curves. The QuikRead CRP reagents are precalibrated, and the calibration curve, which is lot specific, is coded into a magnetic card provided with each kit.

QuikRead CRP plasma compared to	total	y	r
Tina-quant in OD	100	$0.866 + 3.63$	0.996
Tina-quant at Jorvi	157	$0.850 + 3.36$	0.995

b. Matrix comparison:

Whole blood vs plasma comparability

In a comparison of 75 patient samples (CRP range 5-180 mg/L), whole blood and plasma results were found comparable.

Total	y	r
100	$1.047 + -0.21$	0.995

3. Clinical studies:

a. *Clinical sensitivity:*

Study was done at two sites (ORION and Jorvi Hospital) using 100 patient samples and 157 patient samples respectively.

Relative sensitivity at Orion 100.0%.

Relative sensitivity at Jorvi 97.8%

b. *Clinical specificity:*

Study was done at two sites (ORION and Jorvi Hospital) using 100 patient samples and 157 patient samples respectively.

Relative specificity at Orion 98.6%.

Relative specificity at Jorvi 95.4%

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

4. Clinical cut-off:

NA

5. Expected values/Reference range:

Less than 5 mg/L

Guidelines for CRP reference range have been published by an international consensus group (Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Biennu J, et. al. Consensus of a group Professional Sociates and Diagnostic

M. Instrument Name:

QuikRead® 101 Instrument

N. System Descriptions:

1. Modes of Operation:

Manual mode

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ☒ X ☐ or No ☐

3. Sample Identification:

Samples are identified manually. The instrument has a built-in connection for a barcode reader for future applications.

4. Specimen Sampling and Handling:

One mL of buffer is dispensed into a cuvette using the QuikRead 1 mL

Dispenser. 20 uL of whole blood/plasma using a capillary pipette is added into the cuvette. The cuvette is closed tightly using a CRP Reagent Cap and mix by

shaking gently. The cuvette is then placed into the measurement well of the instrument.

5. Assay Types:

Immunoassay

6. Reaction Types:

Photometric and turbidimetric

7. Calibration:

The instrument is factory calibrated. The calibration data defining the overall assay curve or cut-off value for each kit is encoded on a magnetic card. The information is transferred to the instrument by passing the magnetic card through the card reader on the instrument

8. Quality Control:

Quikread CRP control is tailor made for Orion Diagnostica by Sero AS, Norway. The following information is provided:

1. description of matrix and the manufacturing process
2. stability protocol
3. certificate of origin, human additives
4. certificate of origin , origin of the matrix
5. Certificate of Analysis
6. Assignment of values

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Determination Decision Summary.

The following information was provided:

- Antibody production and selection
- Description of the standardization procedure
- Value assignment of the CRP master calibrators
- Value assignment of new CRP lots
- Verification of the correctness of the result level of new reagent lots

P. Conclusion:

Based on the review of the information provided in this 510(k), the Orion QuikRead® CRP kit appears to be **Substantially Equivalent** to devices regulated under 21CFR 866.5270 C-Reactive Protein Immunological Test System, Product code DCK, Class II.