

## 3diag - C1q - TIA

### ANNEX to IFU: *Alinity c* - Application Proposal

REF TD-42551 - C1q Complement - for Turbidimetry  
 using 3diag - C1q - CAL SET ( REF TD-42542 )

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#### GENERAL TAB

##### GENERAL PARAMETERS

Assay Name	<b>C1Q<sup>(*1)</sup></b>	Assay Type	Photometric
Assay Number	System proposes the next available one	Assay Availability	<b>Enabled</b>
Assay Version	ID of assay version	Assay Status	Primary
Date/Time	Date and time of last changes	Run Controls for Reagents by	<b>Lot</b>
Operator	User ID, who modified the definition		

##### REACTION DEFINITION

Reaction Mode	<b>End Up</b>	Main Read Time	<b>37 - 38</b>	Absorbance Range	Not Defined
Primary Wavelength	<b>604</b>	Flex Read Time	Not Defined	Sample Blank Type	<b>Self Blank</b>
Second. Wavelength	Not Defined	Blank Read Time	<b>20 - 21</b>	Blank Assay	Not Defined
Last Read Required	<b>38</b>	Color Corr. Read Time	Not Defined		

##### REAGENT

<b>New Reagent flyout - for Reagents</b>	
Reagent Name	<b>R-C1Q<sup>(*1)</sup></b>
Reagent Type	<b>R1 and R2</b>
R1 bottle - Reaction Buffer - Use	<b>BUF C1Q</b>
R2 bottle - Antiserum Reagent - Use	<b>REAG Ab C1Q</b>
Low Alert	<b>15</b>
Number of Test	<b>85 (260 if 2 kits/cartridge are used<sup>(*2)</sup>)</b>
Onboard Stability	<b>9999 (Not used<sup>(*3)</sup>)</b>

##### Reagents

Reagent Name	<b>R-C1Q</b>	R1 Reagent Volume	<b>80</b>	R2 Reagent Volume	<b>20</b>
Diluent Name	<b>Saline</b>	R1 Water Volume	Not Defined	R2 Water Volume	Not Defined
Diluent Disp. Mode	<b>Type 1</b>	R1 Dispense Mode	<b>Type 1</b>	R2 Dispense Mode	<b>Type 1</b>

##### SAMPLE

<u>Dilution Name</u>	<u>Sample Volume</u>	<u>Dil. Sample Vol.</u>	<u>Diluent Volume</u>	<u>Water Volume</u>	<u>Dilution Factor</u>	<u>Default Dilution</u>
<b>Std 1:15<sup>(*1)</sup></b>	<b>8.0</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)	<b>Yes</b> (Mark as Default)
<b>D1 1:75<sup>(*1)</sup></b>	<b>2.0</b>	<b>2.0</b>	<b>148</b>	Not Defined	75.00 (Informative)	<b>No</b> (Not Mark as Default)

3rd Dilution Not Defined

##### VALIDITY CHECKS

Reaction Check Type	<b>None</b>	Read Time A Range	Not Defined	Calculation Limit	Not Defined
Minimum Absorv.	Not Defined	Read Time B Range	Not Defined	Rate Linearity %	Not Defined
Maximum Absorv. Variation	Not Defined				

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#### CALIBRATION TAB

##### CALIBRATION / VALIDITY CHECKS

Calibration Method	<b>Spline</b> (Recommended)	Adjust Interval Hours	Not Defined	Adjust Level	Not Defined
Full Interval Hours	<b>0</b> (Disabled <sup>(*4)</sup> )	Adjust Type	<b>None</b> <sup>(*5)</sup>	Default Ordering Type	Not Defined
Factor	Not Defined	Maximum Curve Fit	Not Defined	Blank Absorv. Range	Not Defined
Use Cal Factor From	Not Defined	Span Blank	Not Defined	Span Absorv. Range	Not Defined
Expected Cal Factor	Not Defined				
Exp. Cal. F. Toler. %	Not Defined				

##### CALIBRATORS

###### **New Cal Set flyout**

Calibrator Set Name **C1Q CAL <sup>(\*1)</sup>**      Calibrator Set Levels **6**

**NOTE:** The Concentration of the calibrator level **C1Q CAL 1**, used to made the blank, **must be set equal to zero**.

##### **Calibrators**

Calibrator Set Name	Select from menu		Replicates	<b>2</b> (Recommended)	
Cal Level	Sample Volume	Dil. Sample Vol.	Diluent Volume	Water Volume	Dilution Factor
Blank: <b>C1Q CAL 1</b>	<b>1.5</b>	<b>2.0</b>	<b>300</b>	Not Defined	201.00 (Informative)
Cal 1: <b>C1Q CAL 2</b>	<b>8</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 2: <b>C1Q CAL 3</b>	<b>8</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 3: <b>C1Q CAL 4</b>	<b>8</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 4: <b>C1Q CAL 5</b>	<b>8</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 5: <b>C1Q CAL 6</b>	<b>8</b>	<b>2.0</b>	<b>112</b>	Not Defined	15.00 (Informative)

#### RESULT TAB

##### RESULT UNITS

Result Units	<b>mg/dl</b>	Decimal Places	<b>2</b> (Recommended)	Result Unit UCUM	<b>mg/dl</b>
Correlation Factor	<b>1.0000</b>	Intercept	<b>0.0000</b>		

##### RESULT PARAMETERS

Low Linearity	User Defined <sup>(*6)</sup>	High Linearity	User Defined <sup>(*6) (*7)</sup>
Gender and Age Spec. Ranges	User Defined		

##### INTERPRETATION PARAMETERS

Name, Range & Rev. Required User Defined

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#### **RETEST RULES TAB** ( User defined, the proposed parameters have only value as a recommendation )

##### 1st - Retest Rule

Retest Rule Name	C1Q DIL1 <sup>(*1)</sup>	Result Indicator	Select <b>Result Range</b>
Result Range	Set as Cal Set (REF: TD-42542) Level-6 value <sup>(*7)</sup>		
To	Not Defined		
Original Dilution	<b>Std 1:15</b> (Default Dilution)		
<u>Selected Retest Assay</u>	<u>Retest Dilution</u>	<u>Replicates</u>	
<b>C1Q</b>	<b>D1 1:75</b>	<b>1</b>	

#### **NOTES**

- (\*1) Proposal, User defined field.
- (\*2) The number of test per kit can be optimized if 2 kits are transferred into a single container.
- (\*3) We recommend to disable the Onboard Stability check, and re-calibrate when the QC established procedures do not give the expected results. If, after re-calibration, QC established procedures still not giving the expected results then discard the reagents.
- (\*4) We recommend to disable the automatic control of the calibration interval, and re-calibrate when a new batch of reagents is used, or when the QC established procedures do not give the expected results.
- (\*5) The use of the calibration adjustment, with only one or two calibrator levels, is discouraged.
- (\*6) We recommend to define the Linearity Limits as:
  - Low Linearity Limit equal to 0.2 (fixed value), and
  - High Linearity Limit equal to Cal Set (REF: TD-42542) Level-6 value, **divided by 15** (the calibration dilution).
- (\*7) High Linearity Limit and Result Ranges for the retest rules should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42542) with different values is used.