

## 3diag - C1q - TIA

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

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

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#### GENERAL

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Assay	<b>C1Q<sup>(*1)</sup></b>	Assay Type	<b>Photometric</b>
Assay Availability	<b>Enabled</b>	Run Controls for R. by	<b>Lot</b>

##### REACTION DEFINITION

Reaction Mode	<b>End Up</b>	Primary Wavelength	<b>604</b>	Second. Wavelength	Not Defined
Main Read Time	<b>32 - 33</b>	Blank Read Time	<b>18 - 19</b>	Last Read Required	<b>33</b>
Sample Blank Type	<b>Self</b>	Absorbance Range	Not Defined	Color Correction	Not Defined

##### REAGENT / SAMPLE

Reagent	<b>42551</b>	R1 Reagent Volume	<b>140</b>	R2 Reagent Volume	<b>35</b>
Diluent Name	<b>Saline</b>	R1 Water Volume	Not Defined	R2 Water Volume	Not Defined
R1 Dispense Mode	<b>Type 0</b>	R2 Dispense Mode	<b>Type 1</b>		

<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</b>	<b>3.5</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</b>	<b>3.5</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				

#### CALIBRATION

##### CALIBRATION / CALIBRATORS

Calibration Method	<b>Spline</b> (Recommended)	Calibrator Set	<b>C1Q CAL<sup>(*1)</sup></b>	Replicates	<b>2</b> (Recommended)
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**NOTE:** The Concentration of the calibrator level **C1Q CAL 1**, used to made the blank, **must be set equal to zero**.

##### VOLUMES

<u>Cal Level</u>	<u>Sample Volume</u>	<u>Dil. Sample Vol.</u>	<u>Diluent Volume</u>	<u>Water Volume</u>	<u>Dilution Factor</u>
Blank: <b>C1Q CAL 1</b>	<b>1.5</b>	<b>3.5</b>	<b>300</b>	Not Defined	201.00 (Informative)
Cal 1: <b>C1Q CAL 2</b>	<b>8</b>	<b>3.5</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 2: <b>C1Q CAL 3</b>	<b>8</b>	<b>3.5</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 3: <b>C1Q CAL 4</b>	<b>8</b>	<b>3.5</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 4: <b>C1Q CAL 5</b>	<b>8</b>	<b>3.5</b>	<b>112</b>	Not Defined	15.00 (Informative)
Cal 5: <b>C1Q CAL 6</b>	<b>8</b>	<b>3.5</b>	<b>112</b>	Not Defined	15.00 (Informative)

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#### INTERVALS

Full Interval (hours)	Not Defined <sup>(*2)</sup>	Adjust Interval (hours)	Not Defined	
Adjust Type	<b>None</b> <sup>(*3)</sup>	Adjust Level	Not Defined	Default Ordering Type Not Defined

#### VALIDITY CHECKS

Blank Absorv. Range	Not Defined	Span	Not Defined	Span Absorv. Range	Not Defined
Expected Cal Factor	Not Defined	Exp. Cal. F. Toler. %	Not Defined	Maximum Curve Fit	Not Defined

#### RESULTS

Low Linearity	User Defined <sup>(*4)</sup>	High Linearity	User Defined <sup>(*4) (*5)</sup>
Gender and Age Spec. Ranges	User Defined		
Name, Range & Rev. Required	User Defined		
Result Units	<b>mg/dl</b>	Decimal Places	<b>2</b> (Recommended)
Correlation Factor	<b>1.0000</b>	Intercept	<b>0.0000</b>

#### NOTES

- (\*1) Proposal, User defined field.
- (\*2) Calibration curves have a limited validity, which depends on the particular conditions of use. We recommend to disable the automatic control of the calibration interval, and re-calibrate when:
  - a new lot of reagents is used,
  - established internal quality control procedures do not deliver the expected results, or
  - after performing maintenance operations on the analyzer.
- (\*3) The use of the calibration adjustment, with only one or two calibrator levels, is discouraged.
- (\*4) Linearity Limits can be left undefined, as for non-linear calibrations the analyzer automatically controls and flags samples with signals higher than the highest calibrator. If the user wants to use the Linearity Limits, we recommend to define it 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).
- (\*5) High Linearity Limit should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42542) with different values is used.
- (\*6) The number of test per kit can be optimized if 2 kits are transferred into a single container.
- (\*7) It is recommended to retest samples higher than the upper limit of the assay range at 1:75 dilution.