

## 3diag - C5 - TIA

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

**REF** TD-42571 - C5 Complement - for Turbidimetry  
 using **3diag - C5 - CAL SET** ( **REF** TD-42562 )

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#### GENERAL TAB

##### GENERAL PARAMETERS

|               |  |                              |                |
|---------------|--|------------------------------|----------------|
| Assay Name    | <b>C5</b> <sup>(*1)</sup>              | Assay Type                   | Photometric    |
| Assay Number  | System proposes the next available one | Assay Availability           | <b>Enabled</b> |
| Assay Version | ID of assay version                    | Assay Status                 | <b>Primary</b> |
| 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>340</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

###### New Reagent flyout - for Reagents

|                                     |   |
|-------------------------------------|---|
| Reagent Name                        | <b>R-C5</b> <sup>(*1)</sup>                                   |
| Reagent Type                        | <b>R1 and R2</b>  |
| R1 bottle - Reaction Buffer - Use   | <b>BUF C5</b>   |
| R2 bottle - Antiserum Reagent - Use | <b>REAG Ab C5</b>   |
| Low Alert                           | <b>15</b>   |
| Number of Test                      | <b>85</b> (240 if 2 kits/cartridge are used <sup>(*2)</sup> ) |
| Onboard Stability                   | <b>9999</b> (Not used <sup>(*3)</sup> )                       |

##### Reagents

|                    |               |                   |               |                   |               |
|--------------------|---------------|-------------------|---------------|-------------------|---------------|
| Reagent Name       | <b>R-C5</b>   | R1 Reagent Volume | <b>70</b>     | R2 Reagent Volume | <b>30</b>     |
| Diluent Name       | <b>Saline</b> | R1 Water Volume   | <b>23</b>     | 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 1:1</b> <sup>(*1)</sup> | <b>2.5</b>           | Not Defined             | Not Defined           | Not Defined         | 1.00 (Informative)     | <b>Yes</b> (Mark as Default)    |
| <b>D1 1:5</b> <sup>(*1)</sup>  | <b>20</b>            | <b>2.5</b>              | <b>80</b>             | Not Defined         | 5.00 (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 **C5 CAL <sup>(\*1)</sup>** Calibrator Set Levels **6**

**NOTE:** The Concentration of the calibrator level **C5 CAL 1**, used to made the blank, must be set equal to zero.

##### Calibrators

| Calibrator Set Name    | Select from menu |                  | Replicates     | 2 (Recommended) |                      |
|------------------------|------------------|------------------|----------------|-----------------|----------------------|
| Cal Level              | Sample Volume    | Dil. Sample Vol. | Diluent Volume | Water Volume    | Dilution Factor      |
| Blank: <b>C5 CAL 1</b> | <b>1.5</b>       | <b>2.5</b>       | <b>300</b>     | Not Defined     | 201.00 (Informative) |
| Cal 1: <b>C5 CAL 2</b> | <b>2.5</b>       | Not Defined      | Not Defined    | Not Defined     | 1.00 (Informative)   |
| Cal 2: <b>C5 CAL 3</b> | <b>2.5</b>       | Not Defined      | Not Defined    | Not Defined     | 1.00 (Informative)   |
| Cal 3: <b>C5 CAL 4</b> | <b>2.5</b>       | Not Defined      | Not Defined    | Not Defined     | 1.00 (Informative)   |
| Cal 4: <b>C5 CAL 5</b> | <b>2.5</b>       | Not Defined      | Not Defined    | Not Defined     | 1.00 (Informative)   |
| Cal 5: <b>C5 CAL 6</b> | <b>2.5</b>       | Not Defined      | Not Defined    | Not Defined     | 1.00 (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             | <b>C5 DIL1</b> <sup>(*1)</sup>               | Result Indicator  | Select <b>Result Range</b> |
|------------------------------|--|-------------------|----------------------------|
| Result Range                 | Set as Cal Set (REF: TD-42562) Level-6 value | <sup>(*7)</sup>   |                            |
| To                           | Not Defined                                  |                   |                            |
| Original Dilution            | <b>Std 1:1</b> (Default Dilution)            |                   |                            |
| <u>Selected Retest Assay</u> | <u>Retest Dilution</u>                       | <u>Replicates</u> |                            |
| <b>C5</b>                    | <b>D1 1:5</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) 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.
- (\*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 2.0 (fixed value), and
  - High Linearity Limit equal to Cal Set (REF: TD-42562) Level-6 value.
- (\*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-42562) with different values is used.