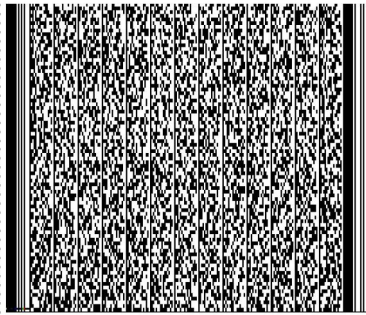
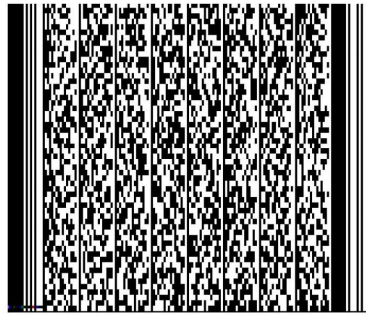


3diag - SAA - OPT Kit

ANNEX to IFU: *Optilite*[®] - Proposal of Application

REF TD-42887 - Serum Amyloid A - KIT - for *Optilite*[®]

Optilite[®] is a registered trademark of *The Binding Site Group Ltd.*, Birmingham, U.K.

| Test parameters | | | | | Page | 1 / 3 |
|--------------------|---------------------|--------------------------|---|-------------------|--|-------------------|
| TD SAA | | Version number 1 , 1 | | Optilite 4 | | |
| | | | | s/n 864000295027 | | |
| Date | 03/04/2024 | User | Test designer | | | |
| Time | 10:22:21 | Software version: | 7.0.2 | | | |
| <i>Info</i> | | | | | | |
| Tag | TD - 42887 | | Barcode 1 | | Barcode 2 | |
| Last time changed | 27/03/2024 17:46 | |  | |  | |
| User name | Test designer | | | | | |
| Full name | Serum Amyloid A | | | | | |
| In use | Yes | | | | | |
| Type | Photometric | | | | | |
| Online name | | | | | | |
| Acceptance | Manual | | | | | |
| Result unit | mg/l | | | | | |
| Number of decimals | 2 | | | | | |
| Correction factor | 1 | | | | | |
| Correction bias | 0 | | | | | |
| Sample type | Serum | | | | | |
| <i>Flow</i> | | | | | | |
| Blank type | Yes | Primary dilution 1 + | 14 | Dispensed volume | 150 | |
| <hr/> | | | | | | |
| Reagent | Reagent | Volume (µl) | Dispense with | Extra volume (µl) | Syringe speed | Replacing reagent |
| | R SAA.2 | 102 | Extra | 20 | Medium | None |
| Barcode ID | Alarm limit (ml) | Onboard stability (days) | | | | |
| 644 | 2,0 | 30 | | | | |
| Reagent | Reagent | Volume (µl) | Dispense with | Extra volume (µl) | Syringe speed | Replacing reagent |
| | R SAA.1 | 33 | Extra | 10 | Slow | None |
| Barcode ID | Alarm limit (ml) | Onboard stability (days) | | | | |
| 645 | 1,0 | 30 | | | | |
| Incubate | Time (sec) | Actual time (sec) | | | | |
| | 300 | 297 | | | | |
| Sample | Volume (µl) | Dispense with | Extra volume (µl) | Extra wash | | |
| | 15 | Extra | 10 | No | | |
| Incubate | Time (sec) | Actual time (sec) | | | | |
| | 18 | 18 | | | | |
| End-point blank | Blank resp. min.(A) | Blank resp. max.(A) | | | | |
| | 0 | * | | | | |
| Incubate | Time (sec) | Actual time (sec) | | | | |
| | 600 | 594 | | | | |

3diag - SAA - OPT Kit

ANNEX to IFU: *Optilite*[®] - Proposal of Application

| Test parameters | | | | | Page | 2 / 3 |
|--------------------------------|----------------------|--------------------------------|-----------------------|---------------------------|---------------------|--------------------------|
| | | TD SAA | | Version number 1 , 1 | Optilite 4 | |
| | | | | s/n 864000295027 | | |
| Date | 03/04/2024 | User | Test designers | | | |
| Time | 10:22:21 | Software version: 7.0.2 | | | | |
| End-point measurement | Main wavelength (nm) | Side wavelength (nm) | Residual net abs. (A) | Delta abs. check min. (A) | | |
| | 510 | None | 0 | * | | |
| Dilution | | Limits | | | | |
| Dilution with | | Diluent | | Measuring range (mg/l) | | Next dilution ratio (1+) |
| Primary dilution 1 + | | 14 | | Min | Max | Low High |
| Neat sample | | | | Primary dilution | 2,000 25,000 | 3,0 59,0 |
| Dispense with | | Extra | | 2nd dilution | * 100,000 | * 299,0 |
| Volume (µl) | | 20 | | 3rd dilution | * 500,000 | * 999,0 |
| Diluent | | | | 4th dilution | * 1.666.667 | * 2999,0 |
| Diluent ID | | Diluent 1 | | Test limit | 0,800 5.000,000mg/l | |
| Calibrator diluent ID | | TD SAA DIL | | Critical limit | * * mg/l | |
| Dispense with | | Extra | | Init. abs. | * * A | |
| Volume (µl) | | 20 | | TVR limit (%) | * | |
| Sample type starting dilutions | | | | | | |
| Sample type | | Dilution | | | | |
| Serum | | 1 + 14 (Primary) | | | | |
| Plasma | | 1 + 14 (Primary) | | | | |
| Urine | | 1 + 14 (Primary) | | | | |
| CSF | | 1 + 14 (Primary) | | | | |
| Oral fluid | | 1 + 14 (Primary) | | | | |
| Whole blood | | 1 + 14 (Primary) | | | | |
| Hemol. blood | | 1 + 14 (Primary) | | | | |
| Other | | 1 + 14 (Primary) | | | | |
| Calibration | | | | | | |
| Calibration type | Logit-Log 4 | | | Abs. error (A) | | * |

3diag - SAA - OPT Kit

ANNEX to IFU: *Optilite*[®] - Proposal of Application

| Test parameters | | | | | Page | 3 / 3 |
|--------------------|-------------------|--------------------------------|----------------------|---------------------|------------|-------|
| TD SAA | | Version number 1 . 1 | | Optilite 4 | | |
| | | | | s/n 864000295027 | | |
| Date | 03/04/2024 | User | Test designer | | | |
| Time | 10:22:21 | Software version: 7.0.2 | | | | |
| Repeat time (days) | 30 | | Rel. error (%) | | | * |
| Points/calibrator | Single | | Factor limit min. | | | * |
| Acceptance | Manual | | Factor limit max. | | | * |
| Nbr | Calibrator | Current lot | Concentration | Dilution 1 + | | |
| 1 | TD SAA Cal | Default | * | 3 | | |
| 2 | TD SAA Cal | Default | * | 4 | | |
| 3 | TD SAA Cal | Default | * | 5 | | |
| 4 | TD SAA Cal | Default | * | 7 | | |
| 5 | TD SAA Cal | Default | * | 10 | | |
| 6 | TD SAA Cal | Default | * | 15 | | |
| 7 | TD SAA Cal | Default | * | 24 | | |
| 8 | TD SAA Cal | Default | * | 49 | | |
| QC | | | | | | |
| Procedure | KIT QC | QC profile | Kit QC | | | |
| Interval type | | In use | Yes | | | |
| Requests | | Acceptance | Manual | | | |
| Time (hh:mm) | 0:00 | Trigger | Manual, Calibration | | | |
| Procedure | Control | Current Lot | Conc. | SD | Req. count | |
| KIT QC | TD SAA HQC | | | | 1 | |
| KIT QC | TD SAA LQC | | | | 1 | |
| Procedure | Nbr of controls | SD multiplier | | | | |
| KIT QC | 1 | 2 | | | | |