

DRI™ TRICYCLICS SERUM TOX APPLICATION



QuidelOrtho Vitros® XT 7600 INTEGRATED SYSTEM, Vitros® 5600 INTEGRATED SYSTEM, AND Vitros® 4600 CHEMISTRY SYSTEM

Reference No. 1128

The DRI Tricyclics Serum Tox Assay is intended for the qualitative and semiquantitative determination of tricyclic antidepressants in human serum, plasma, or urine. **This application sheet is for qualitative use only.**

IVD For In Vitro Diagnostic Use Only
Rx Only

Intended Use



The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen preparation, specimen storage, quality control, and additional performance data. For package inserts, visit www.quidelortho.com > Resources > MicroTip Partnership Assays (MPA).

Ordering Information

Please place your order with QuidelOrtho. Ordering information available on www.quidelortho.com.

Technical Support Information

Contact QuidelOrtho for technical support. Contact information available on www.quidelortho.com.



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Reagent Pack Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 30 days.

Reagents are supplied liquid ready-to-use.

The UDxx reagent pack may be filled up to 12.25 mL of Reagent A in UDxx/A bottle and 3.75 mL of Reagent B in UDxx/B bottle, which provides 76 tests.

| R1 (mL) in UDxx/A | R2 (mL) in UDxx/B | Tests/pack |
|-------------------|-------------------|------------|
| 12.25 mL | 3.75 mL | 76 |

If Splitting: The provided kit configuration will provide 2 UDxx reagent packs with 152 tests.

NOTE: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Special Reagent Packs for User Defined Assays

(Please order from QuidelOrtho; not available from Microgenics)

| Part Number | Description | Quantity |
|-------------|---------------------|------------|
| 680 2246 | UD01 Packs (Empty) | 1 BOX/6PKS |
| 680 2247 | UD02 Packs (Empty) | 1 BOX/6PKS |
| 680 2248 | UD03 Packs (Empty) | 1 BOX/6PKS |
| 680 2249 | UD04 Packs (Empty) | 1 BOX/6PKS |
| 680 2250 | UD05 Packs (Empty) | 1 BOX/6PKS |
| 680 2251 | UD06 Packs (Empty) | 1 BOX/6PKS |
| 680 2252 | UD07 Packs (Empty) | 1 BOX/6PKS |
| 680 2253 | UD08 Packs (Empty) | 1 BOX/6PKS |
| 680 2254 | UD09 Packs (Empty) | 1 BOX/6PKS |
| 680 2255 | UD10 Packs (Empty) | 1 BOX/6PKS |
| 684 4449 | UD11 Packs (Empty) | 1 BOX/6PKS |
| 684 4448 | UD12 Packs (Empty) | 1 BOX/6PKS |
| 684 4445 | UD13 Packs (Empty) | 1 BOX/6PKS |
| 684 4442 | UD14 Packs (Empty) | 1 BOX/6PKS |
| 684 4447 | UD15 Packs (Empty) | 1 BOX/6PKS |
| 684 4444 | UD16 Packs (Empty) | 1 BOX/6PKS |
| 684 4441 | UD17 Packs (Empty) | 1 BOX/6PKS |
| 684 4446 | UD18 Packs (Empty) | 1 BOX/6PKS |
| 684 4443 | UD19 Packs (Empty) | 1 BOX/6PKS |
| 684 4440 | UD20 Packs (Empty) | 1 BOX/6PKS |
| 680 2256 | UDDL1 Packs (Empty) | 1 BOX/6PKS |
| 680 2257 | UDDL2 Packs (Empty) | 1 BOX/6PKS |

**Results and
Data
Interpretation**

For the Qualitative assay, the Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System can report both a unit-less Index number and a NEG / POS classification. The assay is calibrated at the cutoff concentration so that the Index number less than the cutoff value are negative and those greater than the cutoff value are positive.

NOTE: *Qualitative results must only be reported as Negative or Positive. Unit-less Index numbers cannot be used in reportable results.*

**Calibration
Frequency**

It is recommended that recalibration occur after a reagent pack change, a calibrator lot change, and as required following quality control procedures.

DRI Tricyclics Serum Tox Assay – Qualitative QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System Parameters

Full Assay Name: Tricyclics Qual

Version Date: 04/16/2019

Short Assay Name: TCA300

Fluid Type: Serum/Plasma

Assay Model Type: 2 Point Rate

Template: *2Pt R1-S-R2

Cal Model Type: Linear

Calibrator Bottles: 2

Reagent Reps per Cal: 2

Reagent Lot Information

On-Board Stability: 30 Days

Reagent Lot Num: Kit Lot

Shelf Exp. Date: Kit Exp Date

Edit Dilution Parameters

Diluent: DATDIL

Standard Dilution Factor: 1.0

Reflex Dilution: OFF

Dilution Factor: 20.0

Reduction Factor: 1.0

Edit Result Parameters

Units: ng/mL

Number of Qualitative Ranges: 2

Significant Digits: 5 Precision Digits: 1

1. NEGATIVE

User Adjusted Parameters

2. POSITIVE Cutoff cal value or greater

Slope: 1.0 Intercept: 0.0

Report Qualitative Result Outside of Range: Yes

CuveTip Exp Time: 35 Temp Sens : No

Measuring (Reportable) 0 to 10000

(More Assay Params) – Edit 2 Pt Rate Additional Parameters

Initial Abs. Limits: -0.20 to 3.50

Second Abs. Limits: -0.20 to 3.50

Antigen Excess Factor: 9.0

**DRI Tricyclics Serum Tox Assay – Qualitative
 QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600
 System Parameters, *continued***

Edit Protocol Parameters

| Step | Volume | Pack ID | Seconds | Wavelength |
|---------------|--------|---------|---------|------------|
| 1. Reagent | 126 µL | UDxx /A | | |
| 2. Incubation | | | 0.0 | |
| 3. Sample | 6 µL | | | |
| 4. Incubation | | | 304.0 | |
| 5. Reagent | 42 µL | UDxx /B | | |
| 6. Incubation | | | 38.0 | |
| 7. Read | | | | 340 nm |
| 8. Incubation | | | 76.0 | |
| 9. Read | | | | 340 nm |

Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: <u>Cal Kit lot</u> |
|----------|------------|--------------------|------------------------------------|
| 1 | <u>1.0</u> | <u>0.20</u> | Cal value: <u>0</u> |
| 2 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>300</u> |

(More Cal Parm) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Increase

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00 Min Resp. Low: -3.00

Edit Triple Read Parameters

| | Reportable Conc. | Triple Read Limit |
|------------------|------------------|-------------------|
| Reportable Min.: | <u>0</u> | <u>50</u> |
| Critical Conc.: | <u>300</u> | <u>20.0</u> % |
| Reportable Max.: | <u>10000</u> | <u>20.0</u> % |

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