



**Diazyme Kappa FLC (KFLC) Assay
 Application Data Sheet- Export Only
 (Ex. U.S. & Canada)**

QuidelOrtho Vitros® 4600 Chemistry System Parameters

Use the following parameters with calibrator DZ169A-CAL and deionized water for calibration

Configure Assay

Full Assay Name: Kappa FLC Version Date: 07/22/2024
 Short Assay Name: KFLC Fluid Type: Serum
 Assay Model Type: 2 Point Rate Template: 2PT R1-S-R2
 Cal Model Type: Cubic Spline Calibrator Bottles: 6 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: Water Standard Dilution Factor: 1.0
 Reflex Dilution: On Dilution Factor: 20.0
 Reduction Factor: 1.0

Edit Result Parameters

Units: mg/L
 Significant Digits: 6 Precision Digits: 1
 User Adjusted Parameters
 Slope: 1.00 Intercept: 0.00
 Cuve Tip Exp Time: 35 Temp Sens : No

Reference Interval: 0.0 to 900000000
 Supplementary: 0.00 to 900000000
 Reportable Range: 2.3 to 150.0

Edit Additional Parameters

Initial Abs. Limits: -0.200 to 2.700
 Second Abs. Limits: -0.200 to 2.700
 Antigen Excess Factor: 9.0000

Edit Protocol Parameters

Step	Volume	Pack ID	Seconds	Wavelength
1. Reagent	113.0 uL	UDxx /A		
2. Incubation			0.00	
3. Sample	9.0 uL			
4. Incubation			266.00	
5. Reagent	38.0 uL	UD xx/B		
6. Incubation			76.00	
7. Read				575 nm
8. Incubation			256.50	
9. Read				575 nm

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Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: <u>Cal Kit lot</u>
1	<u>1.0</u>	<u>0.20000</u>	Cal value: <u>0.00</u>
2	<u>1.0</u>	<u>0.20000</u>	Cal Value: <u>*</u>
3	<u>1.0</u>	<u>0.20000</u>	Cal value: <u>*</u>
4	<u>1.0</u>	<u>0.20000</u>	Cal Value: <u>*</u>
5	<u>1.0</u>	<u>0.20000</u>	Cal value: <u>*</u>
6	<u>1.0</u>	<u>0.20000</u>	Cal Value: <u>*</u>

Edit Additional Calibration Parameters

Monotonicity: Increase

Max Resp High: 3.000

Min. Resp. High: 3.000

Cal Fit Goodness Limit: N/A

Max Resp. Low: -3.000

Min Resp. Low: -3.000

Calibration Interval: ** Days

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	<u>2.3</u>	<u>6.2</u>
Critical Conc.:	<u>77.3</u>	<u>8.0</u> %
Reportable Max.:	<u>150.0</u>	<u>8.0</u> %

*Value input by operator (variable assigned value for each lot).

**User defined

**It is recommended that recalibration occur after a reagent pack change, after a calibrator lot change, after performance of monthly instrument maintenance, and as required following the laboratory's quality control procedures.

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For *In Vitro* Diagnostic Use Only

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 storage, quality control and additional performance data. For package inserts, visit www.quidelortho.com > Resources > Technical Documentation > MicroTip Partnership Assays (MPAs).

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

Item	Reference Number	Configuration
Diazyme Kappa FLC-148t/kit (Rest of World Only) *Calibrator included*	DZ169A-KY1	R1: 1 x 22 mL R2: 1 x 7 mL Cal: 5 x 1.5 mL
Diazyme Kappa and Lambda FLC – 2 Level Control	DZ169ACON	2 x 3 mL

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

Reagent Pack Storage

Reagents are stable until the labeled expiration date at 2-8°C when stored in the original container.

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

Reagents are supplied liquid, ready to use. The Diazyme Kappa FLC Calibrators and Diazyme Kappa FLC Controls are supplied liquid, ready to use. For calibration, deionized water and the Diazyme Kappa FLC Calibrator 1 – 5 are to be used for calibration.

If Splitting: It is recommended that the reagents be split into 2 UDxx reagent packs containing a sufficient volume for a 30-day period of testing, based on anticipated utilization. The recommended fill volumes for each of the 2 UDxx reagent packs are as follows:

R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack
11.0	3.5	74

2 UDxx reagent packs would be able to perform approximately 148 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.

