



## Diazyme Kappa FLC (KFLC) Assay Application Data Sheet – US & 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: 2.9 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

# Diazyme Kappa FLC (KFLC) Assay QuidelOrtho Vitros® 4600 Chemistry System

## 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>2.9</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.

## Diazyme Kappa FLC (KFLC) Assay QuidelOrtho Vitros® 4600 Chemistry System

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](http://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](http://www.quidelortho.com).

Item	Reference Number	Configuration
Diazyme Kappa FLC-148t/kit (US and CANADA) *Calibrator included*	DZ169A-K	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](http://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.

**Special Reagent Packs for User Defined Assays**  
(Please order from QuidelOrtho)

Reference No.	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

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**Results and Data Interpretation** Refer to the assay insert sheet.

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**Out of Range Condition Codes** A very high analyte sample can produce an absorbance outside the Vitros System photometer range and will result in a CB condition code.

Samples above the calibration curve prediction range, but within the System photometer range, will produce an ER condition code.

A predicted concentration result will not be generated when any of these conditions are posted. Samples must be diluted in accordance with the Kappa Free Light Chain package insert.