OCTET® QKe AND OCTET QK

IQOQ USER MANUAL

INSTALLATION & OPERATION QUALIFICATION PROTOCOLS

Disclaimer

Fortebio reserves the right to change its products and services at any time to incorporate the latest technological developments. This user manual is subject to change without notice.

Limitation

The Fortebio Octet QK^{e} and Octet QK systems are for research use only; not for use in diagnostic procedures.

Trademarks

Octet is a registered trademark of Fortebio, Inc.

P/N 41-0059-PD Rev A

ForteBio's Octet Family of Instruments

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SECTION 1: QUALIFICATION DESCRIPTION FOR THE OCTET QK^{e} AND OCTET QK SYSTEMS

1.1. PURPOSE

The purpose of the Octet QK^{e} and Octet QK systems Installation Qualification and Operation Qualification (IQOQ) document is to provide the methods to verify proper installation and operation of Octet QK^{e} and Octet QK systems prior to their use.

1.2. SCOPE

The document provides detailed methods with illustrations to perform installation and operation qualification of the Octet QK^{e} and Octet QK systems. The qualification process is specific to Octet QK^{e} and Octet QK systems and tailor-made for verification of their performance.

Any aspect of performance of the system in a particular end-user application or assay is not guaranteed by the IQOQ qualification. System performance specific to an end-user application is considered to be a "Performance Qualification (PQ) and is not within the scope of this IQOQ process. Also, validation of the Octet software and Dip and Read™ biosensors fall outside the scope of the IQOQ process.

The current document should be used to qualify only one Octet QKe or Octet QK system. To qualify a second Octet system of any type, a separate IQOQ validation and testing kit must be ordered.

NOTICE	*The Octet QK^{e} and Octet QK systems IQOQ Validation and Testing kit is intended for use with the qualification of one Octet QK^{e} or Octet QK system only. Qualification of a second Octet system of any type requires the purchase of an appropriate second kit.*

1.3. INTRODUCTION

The Octet QK^{e} and Octet QK systems IQOQ user manual includes three sections:

SECTION	DESCRIPTION
SECTION 1: QUALIFICATION DESCRIPTION FOR THE OCTET QK^{e} AND OCTET QK SYSTEMS	DESCRIPTION OF THE OVERALL VALIDATION PROCEDURE OF THE OCTET QK^{e} AND OCTET QK SYSTEMS
SECTION 2: INSTALLATION QUALIFICATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS	DOCUMENTATION AND VERIFICATION OF PROPER INSTALLATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS USING VALIDATION LOGS
SECTION 3: OPERATION QUALIFICATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS	DOCUMENTED QUALIFICATION OF THE OPERATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS TO FACTORY SPECIFICATIONS

1.4. OCTET SYSTEM OVERVIEW

The Octet QK^e and Octet QK systems purchased from Fortebio are provided with a work station, monitor, power supply box and connection cables. Each system is also supplied with the Octet software that consists of two modules, Data Acquisition and Data Analysis. Each module is provided as the latest released version at the time of system purchase.

The Octet QK^e and Octet QK systems utilize ForteBio's proprietary Bio-layer Interferometry (BLI) technology to monitor biomolecular interactions in real-time without the use of labels. Using this optical technique, binding between ligands immobilized on the tip of biosensors and analyte in solution is measured in 96-well plates. A change in optical thickness at the biosensor tip results in a proportional wavelength shift at the detector.

The Octet QK^e and Octet QK systems enable real-time quantitation and kinetic characterization of biomolecular interactions. In quantitation applications, the systems can be used to provide a measure of active protein concentration in solution. In kinetics applications, the systems can be used to measure the association (k_a) and dissociation (k_d) constants, and affinity (K_D) for binding interactions.

To learn more about the Octet platform, visit www.fortebio.com.

In quantitation analysis, each distinct sample concentration produces a unique binding rate. A set of standards with known concentrations is used to generate a standard curve of binding rate vs. concentration. The sample binding rate is compared to the standard curve to derive accurate quantitation information. After the quantitation data is analyzed, a report can be generated that displays the setup, the standard curve, and quantities calculated.

A kinetics assay is a user-specified, multi-step assay that may include the following steps:

- Incubate biosensors in buffer to monitor baseline
- Incubate biosensors in capture molecule wells to load capture protein on biosensors
- Incubate biosensors in buffer to establish another baseline
- Incubate biosensors in analyte sample to measure association
- Incubate biosensors in buffer to monitor analyte dissociation

Binding curves are generated in real-time during a run and displayed in the Runtime binding chart window in Octet Data Acquisition software. The kinetic rate constants for the binding interaction are calculated by curve-fitting in Octet Data Analysis software. To learn more about the use of the Octet QK^e and Octet QK systems, please refer to the User Guides provided in the Help menu of Octet software.

1.5. QUALIFICATION PROCEDURE

- The Octet QK^e and Octet QK systems shall be validated using the validation logs to record the information.
- Unused portions of the protocol shall be crossed out and/or marked "N/A".
- To qualify multiple systems, a separate log shall be used for each system.
- Qualification may be considered acceptable once all steps and supporting documents have been completed and all discrepancies resolved.

1.6. QUALIFICATION REFERENCES

- Octet System Data Acquisition Software User Guide
- Octet System Data Analysis Software User Guide

1.7. COMMENTS (INTENTIONALLY LEFT BLANK)

1.8. PRE-APPROVALS

By signing this page, the following individuals certify that they have reviewed this document prior to the commencement of qualification testing.

AUTHORIZED FORTEBIO REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

SECTION 2: INSTALLATION QUALIFICATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS

2.1. PURPOSE

The Octet QK^{e} and Octet QK systems Installation Qualification procedure provides documented verification that the correct system was ordered, delivered, and installed according to ForteBio specifications. If the qualification is being performed during the installation of the Octet QK^{e} or Octet QK system, use the procedure described in this section to perform the installation and to record the process. If the Octet QK^{e} and Octet QK systems were previously installed, use this section to record and verify details of the installation.

2.2. USER INFORMATION

Record the name, institution and location information of the primary user of the Octet QK^{e} or Octet QK system.

NAME:
INSTITUTION:
LOCATION:

2.3. ORDER VERIFICATION

Attach a copy of the purchase order and invoice for the Octet QK^{e} or Octet QK system to the IQOQ User Manual. These documents should be provided by the customer. Verify that the correct Octet system was ordered and delivered.

2.4. RECEIVING INSPECTION

1.1. Unpack the boxes containing the Octet system components.

1.2. Find the Packing Slip and save it for the inspection process.

1.3. Remove all components from the boxes and place them on a bench top.

1.4. Inspect the back panel of the Octet system. Record the model number and serial number from the product label on the back panel in Table 2.1 of this document.

1.5. Likewise, record the model number and serial number for the computer and monitor devices in the shipment.

TABLE 2.1 VERIFICATION OF COMPONENT MODEL & SERIAL NUMBERS

ITEM RECEIVED	MODEL NO.	MODEL NO. MATCH PACKING SLIP? (CIRCLE ONE)	SERIAL NO.	SERIAL NO. MATCH PACKING SLIP? (CIRCLE ONE)
MONITOR		YES NO		YES NO
WORKSTATION		YES NO		YES NO
OCTET INSTRUMENT		YES NO		YES NO

1.6. Verify that the model and serial numbers for all three components match that listed on the Packing Slip.

1.7. Circle YES or NO as appropriate against each entry in Table 2.1.

1.8. Place all contents of each box on a bench top.

1.9. Using the checklists in Table 2.2 to Table 2.4, confirm that all of the required components are included.

1.10. Document any missing items or damage in the appropriate table.

*1.11. Record any corrective actions taken in **Section 2.7. Comments**.*

1.12. Share your comments with Fortebio's technical support either by calling them at 1-888-OCTET-75 or emailing to support@fortebio.com.

TABLE 2.2 MONITOR BOX CHECKLIST

CHECK IF RECEIVED	ITEM
	LCD MONITOR
	POWER CABLE
	ANALOG MONITOR CABLE 1
	ANALOG MONITOR CABLE 2

TABLE 2.3 WORKSTATION CHECKLIST

CHECK IF RECEIVED	ITEM
	WORKSTATION
	KEYBOARD
	POWER CABLE
	MOUSE
	DISPLAY PORT TO DVI ADAPTER

TABLE 2.4 OCTET INSTRUMENT AND ACCESSORIES CHECKLIST

CHECK IF RECEIVED	OCTET QK[e]	OCTET QK
	OCTET QK[e] INSTRUMENT	OCTET QK INSTRUMENT
	CABLE BUNDLE	CABLE BUNDLE
	POWER SUPPLY BOX WITH DC POWER CABLE	N/A
	AC POWER CABLE*	AC POWER CABLE*
	POWER STRIP[#]	N/A
	SOFTWARE CD	SOFTWARE CD
	INSTRUMENT BACKUP CD	INSTRUMENT BACKUP CD
	MOUSE PAD	MOUSE PAD
	SOFTWARE LICENSE	SOFTWARE LICENSE

*If the country in which the system is being installed is outside the United States, the accessories to the Octet system should include three additional power cables suitable for use with power sources in the geographical region, one each for the Power supply box (Octet QK[e]) or Octet instrument (Octet QK), monitor and computer.

[#] A power strip is provided with the Octet QK[e] system only to customers within the United States.

2.5. DOCUMENTATION

The documents listed in Table 2.5 may be used when needed as guides in the installation, operation, and maintenance of the Octet system.

TABLE 2.5 DOCUMENTS CHECKLIST

DOCUMENTS
OCTET SYSTEM DATA ACQUISITION SOFTWARE USER GUIDE
OCTET SYSTEM DATA ANALYSIS SOFTWARE USER GUIDE

NOTICE	*Print copies of these documents are not included in the Octet system package. These user guides can be found in the Help menu of the Octet software modules and in the CD accompanying the package.*

2.6. COMMENTS (PAGE INTENTIONALLY LEFT BLANK)

2.7. SETTING UP THE OCTET QK^e AND OCTET QK SYSTEMS

1.1. Place the Octet instrument on a work bench or table where it is to be installed. The work surface should support at least 200 lbs weight and be free of shock and vibration sources such as centrifuges. ForteBio's Sidekick systems may be installed on the same work bench.

1.2. Connect one end of each communication cable to the Octet instrument back panel (Figure 2.1 for Octet QK^e or Figure 2.2 for Octet QK). Each cable is labeled with the port it should be plugged into.

1.3. Place the workstation within four feet of the Octet instrument.

1.4. Set up the monitor, keyboard, and mouse. Connect these accessories to the workstation as shown on the label affixed to the workstation.

1.5. Connect the other ends of the communication cables to the workstation (Figure 2.3 for Octet QK^e or Figure 2.4 for Octet QK). Each cable is labeled with the port it should be plugged into.

1.6. Lift up the door of the Octet system and if present, remove the shipping bracket. Remove all screws of the shipping bracket.

1.7. Inspect the power cables to ensure they are appropriate for local voltage requirements.

1.8. Inspect the workstation to ensure it has been switched to local voltage.

1.9. If setting up an Octet QK^e system:

1.9.1. Place the power supply box within four feet of the Octet QK^e system.

1.9.2. Connect the power supply box to the Octet QK^e system with the DC power cable.

1.9.3. Connect the power supply box, workstation and monitor to the power strip using their respective power cables.

1.10. If setting up an Octet QK system:

1.10.1. Connect the Octet QK system, workstation and monitor to the power strip using their respective power cables.

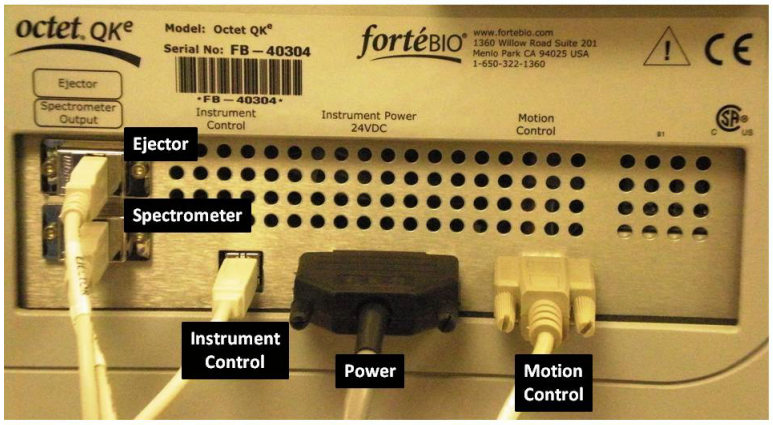


FIGURE 2.1 OCTET QK[e] INSTRUMENT BACK PANEL, COMMUNICATION CABLE CONNECTIONS

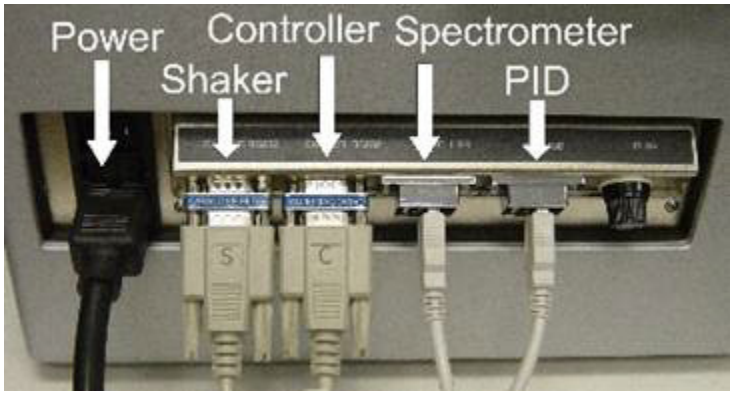


FIGURE 2.2 OCTET QK INSTRUMENT BACK PANEL, COMMUNICATION CABLE CONNECTIONS

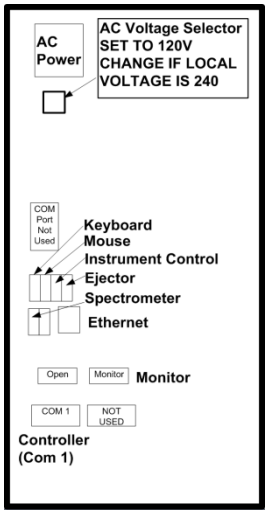


FIGURE 2.3 OCTET QK[e] WORKSTATION CONNECTIONS

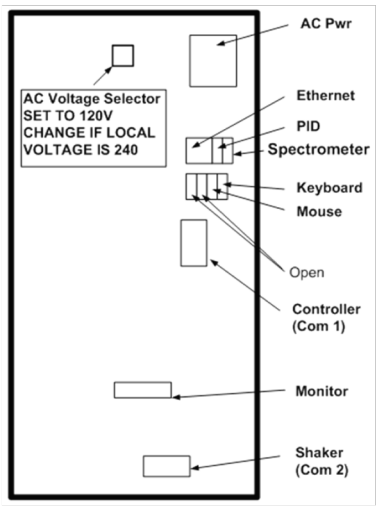


FIGURE 2.4 OCTET QK SYSTEM WORKSTATION CONNECTIONS

2.8. COMMUNICATION VERIFICATION

1.1. Turn on the power strip.

1.2. Turn on the workstation.

1.3. Allow it to finish starting up before proceeding.

1.4. Turn on the Octet instrument.

1.5. Confirm that the green LED on the front panel comes on.

1.6. Wait for 1 minute to allow the USB devices to be recognized by the workstation.

NOTICE	*The initialization process can take about one minute to complete. Please wait until completion to proceed to next step.*

*1.7. Start the Octet Data Acquisition software by double-clicking the acquisition software icon, or select data acquisition from the **Fortebio** folder in the start menu.*

*1.8. The Octet instrument proceeds through the initialization routine. When initialization is successful, the Instrument Status Window (Figure 2.5) displays the message "Ready". Record any corrective actions under **Comments** at the end of this section.*

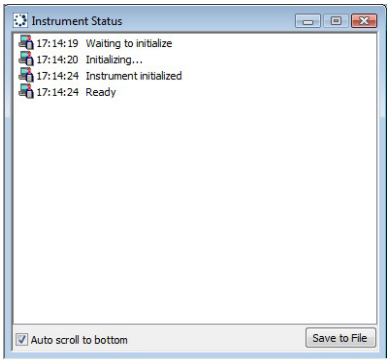


FIGURE 2.5. INSTRUMENT STATUS WINDOW IN OCTET DATA ACQUISITION SOFTWARE.

2.9. SOFTWARE VERIFICATION

*1.1. In the Octet data acquisition software, select **Help > About ForteBio Data Acquisition...** on the menu bar.*

1.2. In the pop-up screen that appears, find and record the software version number in Table 2.6. To do this, write down the numbers that follow the words "Version:" as shown in Figure 2.6.

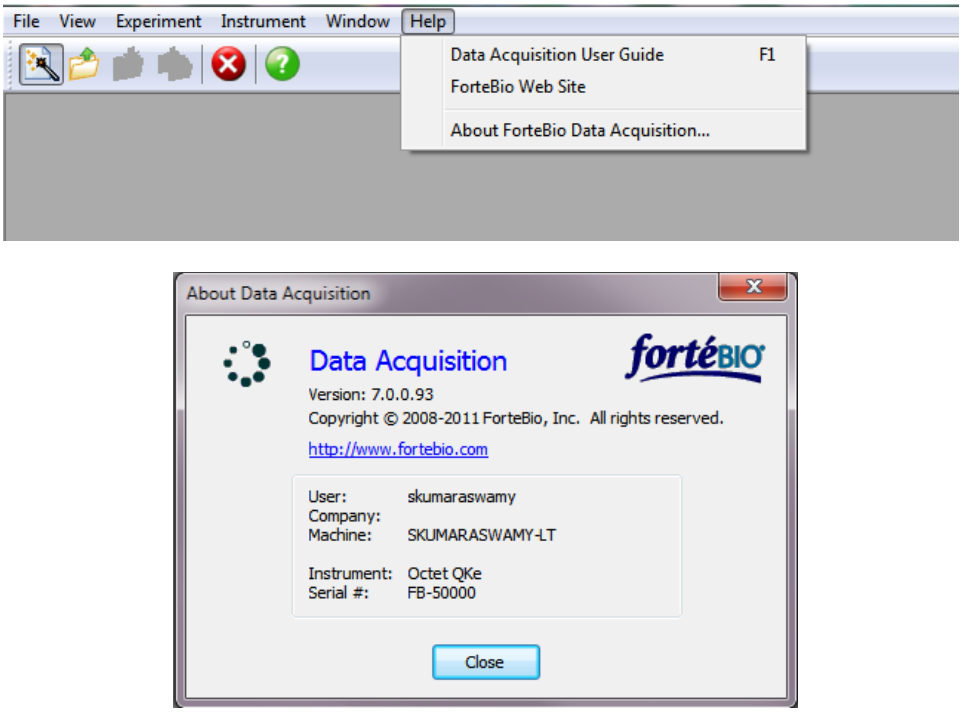


FIGURE 2.6. FIND OCTET DATA ACQUISITION VERSION NUMBERS ON YOUR OCTET SYSTEM AND RECORD THEM IN TABLE 2.6.

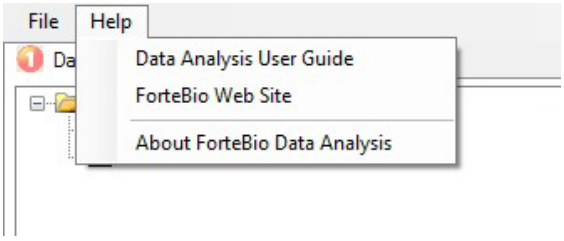
TABLE 2.6 SOFTWARE VERIFICATION INFORMATION

ITEM	VERSION NUMBER
OCTET SYSTEM DATA ACQUISITION	
OCTET SYSTEM DATA ANALYSIS	

1.3. *Open Octet data analysis software by double-clicking the Octet data analysis icon on your desktop, or by selecting data analysis from the **Fortebio** folder in the start menu.*

1.4. *In data analysis software, select **Help> About Fortebio data analysis** on the menu bar.*

1.5. *In the pop-up screen that appears, find and record the software version number in Table 2.6. To do this, write down the numbers that follow the words "Version:" as shown in Figure 2.7.*



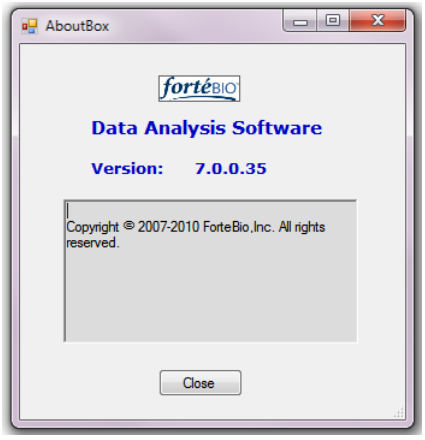


FIGURE 2.7. FIND OCTET DATA ANALYSIS SOFTWARE VERSION NUMBERS ON YOUR OCTET SYSTEM AND RECORD THEM IN TABLE 2.6.

2.10. INSTRUMENT LOG

1.1. *Locate the Instrument Status Window in Octet data acquisition software (Figure 2.5).*

1.2. *If the window is not open, go to the menu bar and click on **Instrument Status** under the **View** option.*

1.3. *Click on the **Save to File** button to save the log file.*

1.4. *Open the saved file in Notepad.*

1.5. *Print, sign and date the instrument log.*

1.6. *Attach the log to the Octet IQOQ User manual.*

2.11. COMMENTS (PAGE INTENTIONALLY LEFT BLANK)

2.12. INSTALLATION QUALIFICATION SIGN OFF

All steps required for the Octet system Installation Qualification have been completed, documented and reviewed. All discrepancies noted during Installation Qualification have been satisfactorily resolved. The installation of the Octet system is hereby considered qualified.

AUTHORIZED FORTEBIO REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

SECTION 3: OPERATION QUALIFICATION OF THE OCTET QK^{e} AND OCTET QK SYSTEMS

3.1. PURPOSE

The purpose of the operation qualification protocol is to verify that:

- The Octet system is fully functional after installation. Functionality is tested for use of the system in quantitation and kinetics analyses.
- Consistent and reproducible results are obtained within product specifications.

3.2. METHOD

The Operation Qualification (OQ) of the Octet QK^{e} and Octet QK systems is performed in two stages.

- Quantitation Qualification (QQ)
- Kinetics Qualification (KQ)

IT IS RECOMMENDED THAT THE QUANTITATION QUALIFICATION BE PERFORMED FIRST FOLLOWED BY THE KINETICS QUALIFICATION.

3.3. MATERIALS REQUIRED FOR OPERATION QUALIFICATION

All reagents, biosensors and microplates required for the qualification are provided in the Octet QK^{e} and Octet QK Validation and Testing kit. Use one bottle of each buffer reagent in the list below to start the qualification tests. Keep the remaining bottles refrigerated until needed.

- IQOQ Compact disk (IQOQ CD)
- Octet QK^{e} and Octet QK systems IQOQ User Manual
- Protein A biosensors – 1 tray of 96 biosensors
- Streptavidin biosensors – 1 tray of 96 biosensors
- IgG Calibrators set extended range
- Biotin-Protein A – 1 bottle of 250 µg/mL
- Sample Diluent – 2 bottles
- 10X Kinetics Buffer – 2 bottles
- Regeneration Buffer – 1 bottle
- PBS, pH 7.4 – 2 bottles
- 96-well, black, flat-bottom, polypropylene (Greiner Bio-one, #665209) microplates – 8 microplates

The following materials are required for the Operation Qualification, but are not provided in the Octet QK^e and Octet QK Validation and Testing kit. These materials should be provided by the customer.

- Micropipettors, various standard volumes
- Pipette tips, various standard sizes
- Sharps waste container

3.4. QUANTITATION QUALIFICATION

Quantitation qualification is performed using the BASIC QUANTITATION WITH REGENERATION METHOD in Octet data acquisition software which evaluates the Octet system in the assay of human IgG samples with the aid of Fortebio's Protein A biosensors. The person performing the qualification tests is strongly advised to follow the procedures described in this document for the qualification.

NOTICE	*The Octet system must be powered on with the door closed for at least 1 hour before starting this test. Operation Qualification assays require ambient temperature ≤ 26°C in order to maintain default assay temperature of 30°C.*

3.4.1. OVERVIEW OF THE METHOD

- The IgG calibrators (human IgG samples at various concentrations) are assayed in a 96-well microplate to construct a standard curve.
- Three of the calibrator solutions (10, 100 and 500 µg/mL concentrations) are set up as "unknown" samples to interpolate concentration values from the standard curve in Octet data analysis software.
- Regeneration and neutralization are performed to re-use the Protein A biosensors between each measurement cycle.
- Data analysis is performed to measure the %CV values of the 8 replicates measured for each of the "unknown" samples. A criterion of %CV ≤ 10 is employed to evaluate PASS or FAIL of the Octet QK^e and Octet QK systems for quantitation qualification.

NOTICE	*The Quantitation Qualification should be performed only with reagents, biosensors and microplates provided with the Octet QKe and Octet QK Validation and Testing kit.*

3.4.2. DATA ACQUISITION (EXPERIMENT SET UP AND RUN) PROTOCOL

1. *Set up experiment in Octet data acquisition software.*

NOTICE	*Use the method files provided in the CD for proper execution of the qualification protocol. If you are unable to access the files from the Octet QKe and Octet QK IQOQ CD, contact ForteBio Technical Support by emailing to support@fortebio.com or by calling 1-888-OCTET-75.*

1.1. *Confirm that the instrument has been on for at least one hour.*

1.2. *Load the IQOQ CD on the computer controlling the Octet system.*

1.3. *Click on **File** in the menu options in Octet data acquisition software and choose **Open Method File...**.*

1.4. *If you are running Octet Data acquisition software v7.X, locate the **IQOQ_Octet QKe_Quantitation_v7.fmf** or **IQOQ_Octet_QK_Quantitation_v7.fmf** method file, as appropriate for the system being qualified.*

1.4.1. *On the IQOQ CD, go to SOFTWARE V7 folder.*

1.4.2. *Go to the **QUALIFICATION METHOD FILES** folder.*

1.4.3. *Click on the **IQOQ_Octet QKe_Quantitation_v7.fmf** file or the **IQOQ_Octet QK_Quantitation_v7.fmf** file, as appropriate for the system being qualified.*

1.5. *If you are running Octet data acquisition software v6.X or v4.X, locate the **IQOQ_Octet QKe_Quantitation_v4-6.fmf** or the **IQOQ_Octet QK_Quantitation_v4-6.fmf** method file, as appropriate for the system being qualified.*

1.5.1. *On the IQOQ CD, go to SOFTWARE V6 folder.*

1.5.2. *Go to the **QUALIFICATION METHOD FILES** folder.*

1.5.3. *Click on the **IQOQ_Octet QKe_Quantitation_v4-6.fmf** file or the **IQOQ_Octet QK_Quantitation_v4-6.fmf** file, as appropriate for the system being qualified.*

1.6. *Click the **Open** button to load the method file. See **Section 2: Installation Qualification of the Octet QK^e and Octet QK System, Sub-section 2.9 Communications Verification** to learn how to open Octet data acquisition software window.*

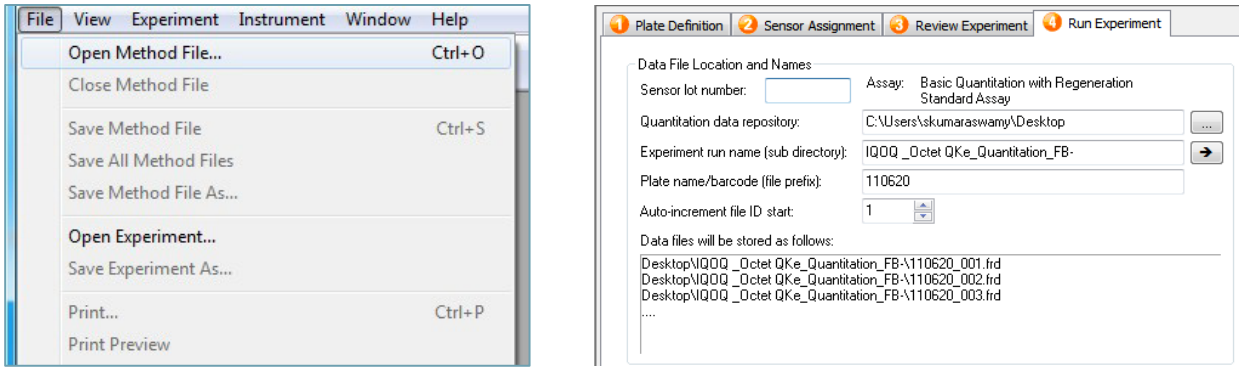


FIGURE 3.1. OCTET DATA ACQUISITION SOFTWARE ACTIONS TO SET UP QUANTITATION QUALIFICATION EXPERIMENT. NOTE: FIGURE SHOWS OCTET DATA ACQUISITION SOFTWARE V6.X. SENSOR LOT NUMBER INPUT IS DONE IN THE SENSOR ASSIGNMENT TAB IN OCTET DATA ACQUISITION SOFTWARE V7.X.

1.7. If you are running Octet Data Acquisition software v7.X, to enter Sensor lot number information:

*1.7.1. Click on **Tab 2, Sensor Assignment**.*

*1.7.2. In the table, enter the lot number under the **Lot Number** column. The lot number of the Protein A biosensors used in the experiment can be found on the biosensor tray pouch label.*

1.8. If you are running Octet Data Acquisition software v6.X or v4.X, to enter Sensor lot number information:

*1.8.1. Click on **Tab 4, Run Experiment**.*

*1.8.2. In the **Sensor lot number:** field, enter the lot number (Figure 3.1). The lot number of the Protein A biosensors used in the experiment can be found on the biosensor tray pouch label.*

*1.9. In the **Quantitation data repository:** field, enter the directory location where you prefer to save the qualification data files. It is recommended that the repository be located on a local drive.*

2. Prepare biosensor tray.

2.1. Prepare a pre-wet microplate by adding 200 µL of Sample Diluent per well to all wells in column 1 of a 96-well microplate.

2.2. Remove the clear lid of the Protein A biosensor tray.

2.3. Lift the green biosensor rack carefully out of the blue biosensor tray holder avoiding touching of the biosensor tips on any solid surface.

2.4. Place the pre-wet plate inside the blue biosensor tray holder.

2.5. Carefully lower the green biosensor rack on top of the pre-wet microplate in the biosensor tray holder to begin hydrating the biosensors in column 1.

2.6. Load the entire ensemble, including the blue biosensor tray holder on to the biosensor tray location in the Octet system (Fig 3.2).

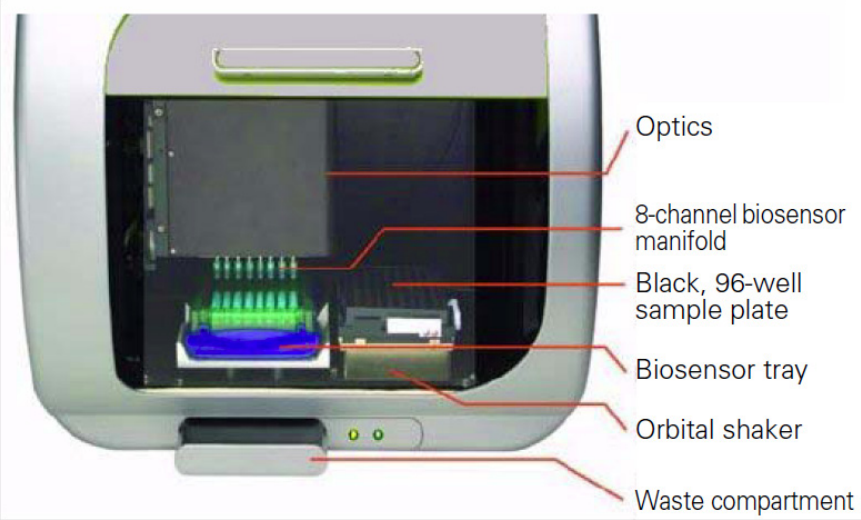


FIGURE 3.2. OCTET QK^{e} AND OCTET QK SYSTEMS, DOOR OPEN.

3. Prepare sample microplate.

3.1. Shake or vortex the tubes containing the IgG calibrator set to ensure sufficient mixing.

*3.2. Pipet 200 µL of the calibrator solutions to a 96-well microplate. Use Table 3.1 or sample plate table in **Tab 1, Plate Definition** of method file in Octet data acquisition software to determine sample locations.*

3.3. Pipet 200 µL of Regeneration Buffer to wells marked "R".

3.4. Pipet 200 µL of Sample Diluent to wells marked "N". Sample Diluent acts as the pH neutralization buffer.

TABLE 3.1 SAMPLE MICROPLATE MAP, IgG CALIBRATOR SOLUTIONS (µg/mL) FOR QUANTITATION QUALIFICATION.

	1	2	3	4	5	6	7	8	9	10	11	12
A	1	700	10	100	500						R	N
B	3	500	10	100	500						R	N
C	10	300	10	100	500						R	N
D	30	100	10	100	500						R	N
E	100	30	10	100	500						R	N
F	300	10	10	100	500						R	N
G	500	3	10	100	500						R	N
H	700	1	10	100	500						R	N

3.5. Remove any bubbles that may be present in the microplate.

3.6. Load the sample plate in the sample plate location on the plate stage of the Octet system (Figure 3.2).

4. Start the experiment.

4.1. Ensure at least 10 minutes of hydration of the biosensors in the pre-wet microplate before starting the experiment.

*4.2. Go to Tab 4, **Run Experiment** in Octet data acquisition software.*

*4.3. Press the **GO** button to start the experiment.*

4.4. The experiment should be complete in about 30 minutes. After completion, proceed to data analysis.

FIGURE 3.3. GO BUTTON IN TAB 4, RUN EXPERIMENT OF OCTET DATA ACQUISITION SOFTWARE.

3.4.3. DATA ANALYSIS PROTOCOL

1. Load data into Octet data analysis software.

Note: The quantitation qualification data analysis protocol is different for systems running Octet software v7.X and software v6.X/4.X. Mainly, Octet software v7.X allows replicate groups to be set up so that averages, standard deviations and %CV values are calculated within Octet data analysis software. In Octet software v6.X and v4.X, the statistical parameters are typically calculated by first exporting the data to Microsoft Excel software and using Excel for the calculations.

*1.1. To perform data analysis, open Octet data analysis software by double-clicking the analysis software icon or from the **Fortebio** folder in the **Start** menu.*

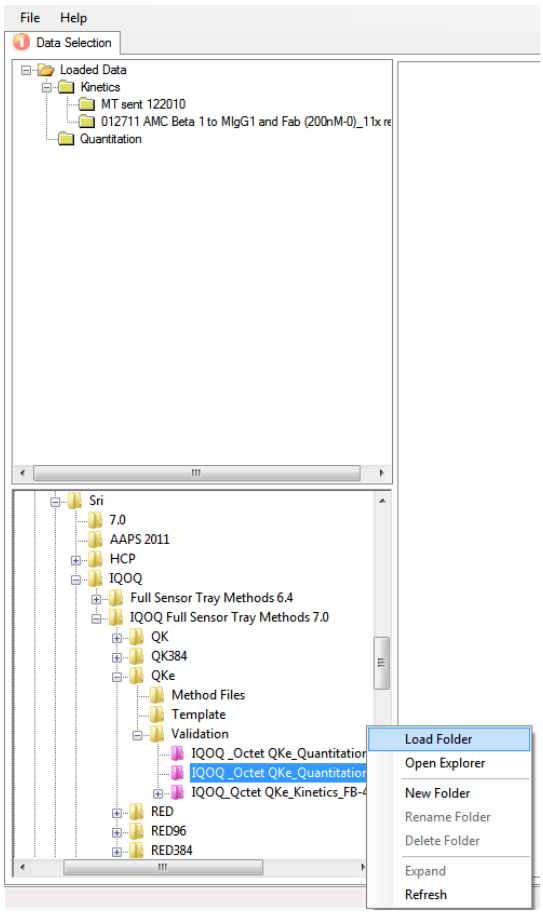


FIGURE 3.4. LOADING A FOLDER IN OCTET DATA ANALYSIS SOFTWARE.

*1.1. In **Tab 1**, **Data Selection**, lower left-hand side window, select the experiment folder created from the quantitation qualification experiment (Figure 3.4).*

*1.2. Right-click the selection and choose **Load Folder** option. This action will populate the folder in the top left-hand side window under the **Quantitation** folder.*

*1.3. Click on the folder name in the **Loaded Data** window. This action loads the experimental data into the data analysis software.*

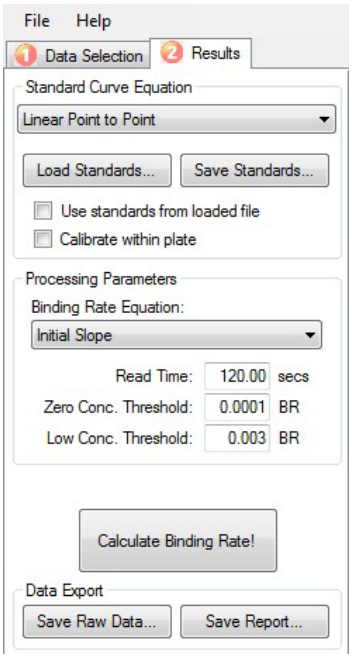


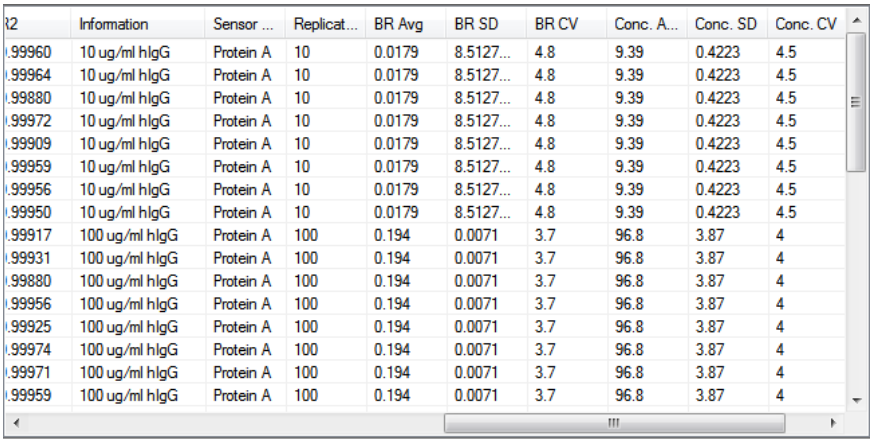
FIGURE 3.5. DATA PROCESSING IN OCTET DATA ANALYSIS SOFTWARE.

2. Process data in Octet data analysis software. If using Octet data analysis software v7.X:

*2.1. Click on the **Results** tab (Figure 3.5).*

*2.2. Click on **Calculate Binding Rate!** This action outputs calculated results for the experiment.*

2.3. Scroll the results table (Figure 3.6) to find the Conc. Avg, Conc. CV values calculated by Octet data analysis software for the three unknown samples.



R2	Information	Sensor ...	Replicat...	BR Avg	BR SD	BR CV	Conc. A...	Conc. SD	Conc. CV
.99960	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99964	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99880	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99972	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99909	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99959	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99956	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99950	10 ug/ml hIgG	Protein A	10	0.0179	8.5127...	4.8	9.39	0.4223	4.5
.99917	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99931	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99880	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99956	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99925	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99974	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99971	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4
.99959	100 ug/ml hIgG	Protein A	100	0.194	0.0071	3.7	96.8	3.87	4

FIGURE 3.6. RESULTS TABLE IN DATA ANALYSIS SOFTWARE V7.X.

3. Process data in Octet data analysis software. If using Octet data analysis software v6.X or v4.X:

*3.1. Click on the **Results** tab.*

*3.2. Click on **Calculate Binding Rate!** This action outputs calculated results for the experiment.*

*3.3. Click on **Save Report** button to export data (Figure 3.5).*

*3.4. In the pop-up window, click on **Save** button. This action saves the report as **ExcelReport.xls** file in the experiment folder and opens the report in Microsoft Excel.*

*3.5. Go to the ExcelReport.xls file in the Microsoft Excel software window on your monitor. Click on the tab that begins with the name: **IQOQ Octet QKe Quan** or **IQOQ Octet QK Quan**, as appropriate for the system being qualified.*

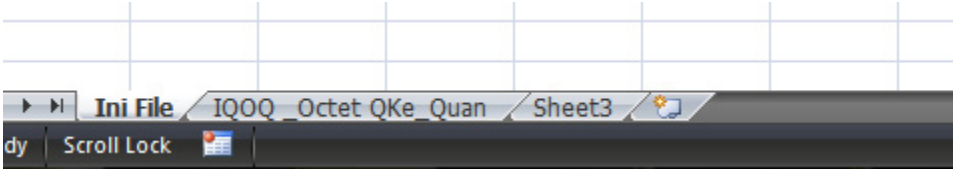


FIGURE 3.7. CLICK ON IQOQ_OCTET QKe_QUAN TAB IN EXCEL SOFTWARE.

3.6. Scroll down to the tabular data section adjacent to the plate map and highlight all of the data below the column headers.

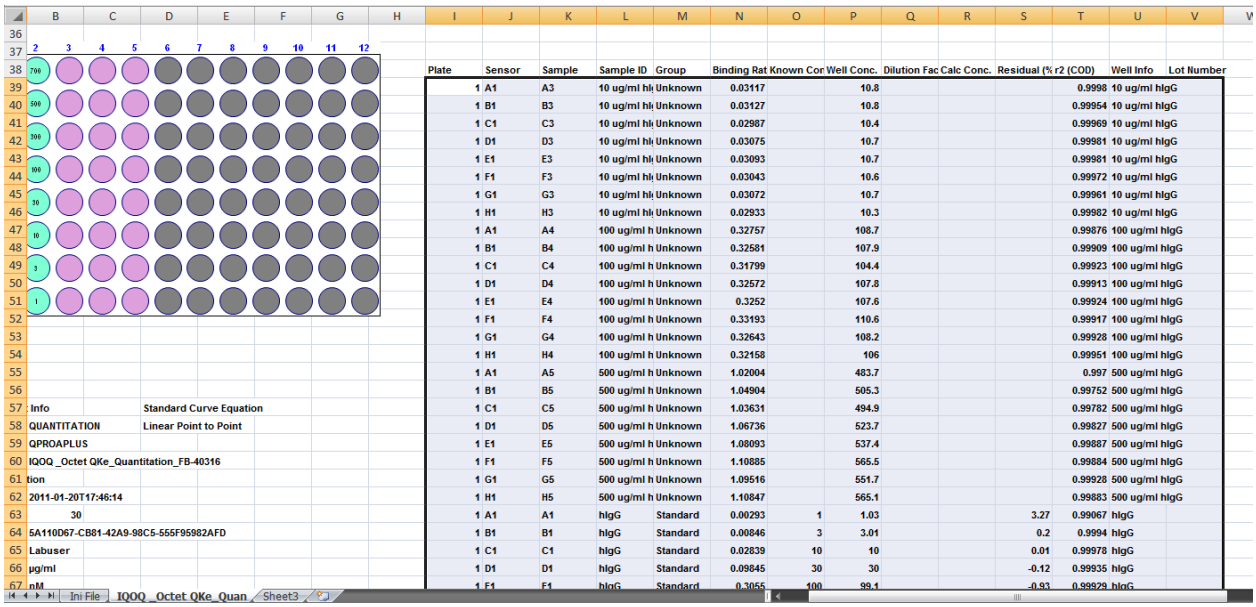


FIGURE 3.8. SELECT ALL DATA BENEATH THE COLUMN HEADERS.

*3.7. Click on the **Copy** button to copy the selected data.*

*3.8. Open the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file from the Octet IQOQ CD.*

*3.9. Go to the tab named **Paste Quantitation data here**.*

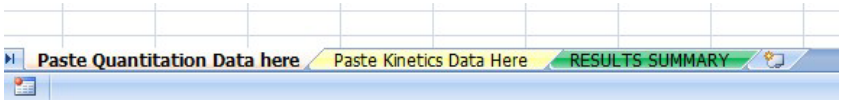


FIGURE 3.9. WORKSHEET TABS IN IQOQ_OCTET QKe_QK_EXCEL CALCULATIONS_V4-6.XLSX FILE.

*3.10. Paste the copied data into the tab starting at **Cell A5**.*

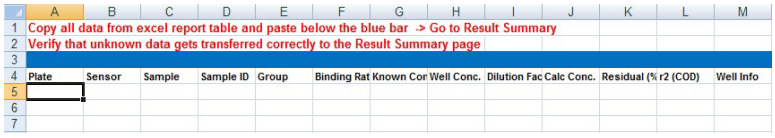


FIGURE 3.10. PASTE THE COPIED DATA BELOW THE COLUMN HEADERS STARTING IN CELL A5.

*3.11. Go to the tab named **RESULTS SUMMARY** in the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file.*

*3.12. In the table titled **Octet QK/QKe Quantitation Qualification Summary**, calculated averages and %CV for the three "unknown' sample concentrations used in the quantitation qualification experiment are shown. An indication of **Pass** or **Fail** also shows in the table.*

*3.13. Save the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file to the local drive.*

*3.14. Print all data in the **Ini file** and **IQOQ Octet QKe Quan** or **IQOQ Octet QK Quan** tab of the **ExcelReport.xlsx** file, as appropriate for the system being qualified.*

3.15. The person performing the qualification test should sign and date the document.

3.16. Attach the document to the Octet QKe and Octet QK IQOQ User Manual.

4. Evaluate data and record results.

4.1. Record the average and %CV values for the three "unknown" concentrations in Table 3.2 of the Octet QK^e and Octet QK IQOQ User Manual.

*4.2. Write down the **Pass** or **Fail** information for each concentration in Table 3.2 using the criterion of Conc. CV ≤ 10. The Octet system passes quantitation qualification only when all three concentrations satisfy this criterion.*

NOTICE	*The CONC.CV values at all three concentrations have to satisfy the criterion of CONC.CV ≤ 10 in order for the Octet system to pass quantitation qualification.*

TABLE 3.2. MEASURED IgG CALIBRATOR CONCENTRATIONS IN 96-WELL MICROPLATE. IF CONC. CV VALUES ARE ≤ 10, THE QUANTITATION QUALIFICATION PASSES.

CONC. (µg/mL)	10	100	500
CONC. AVG			
CONC. CV			
PASS?	YES NO	YES NO	YES NO

3.4.4. REPEAT QUANTITATION QUALIFICATION

If the Octet system passed quantitation qualification, a repeat test is not needed. Proceed to Kinetics Qualification. In the event of a failed quantitation qualification, consult with a Fortebio Technical Support representative to determine if a repeat test is required. The Octet QK^{e} and Octet QK IQOQ Validation and Testing kit contains enough biosensors, reagents and microplates to perform a repeat test.

Do not reuse any reagents from the microplates. Discard the used microplates and reagents, and take fresh microplates from the IQOQ Validation and Testing kit for the repeat test.

NOTICE	*Do not reuse any reagents from the microplates. Discard the used microplates and reagents, and take fresh microplates from the IQOQ Validation and Testing kit for the repeat test.*

Since the first column of biosensors in the Protein A biosensor tray are now empty, the second column of biosensors should be used in the repeat test. Follow the protocol described in **Section 3.4.2. Data Acquisition (Experiment Set Up and Run) Protocol**, with the exception of replacing **Steps 1.4** and **1.5** with the following:

*1.4. If you are running Octet Data acquisition software v7.X, locate the **IQOQ_Octet QKe_Quantitation_Repeat_v7.fmf** or **IQOQ_Octet_QK_Quantitation_Repeat_v7.fmf** method file, as appropriate for the system being qualified.*

1.4.1. On the IQOQ CD, go to SOFTWARE V7 folder.

*1.4.2. Go to the **QUALIFICATION METHOD FILES** folder.*

*1.4.3. Click on the **IQOQ_Octet QKe_Quantitation_Repeat_v7.fmf** file or the **IQOQ_Octet QK_Quantitation_Repeat_v7.fmf** file, as appropriate for the system being qualified.*

*1.5. If you are running Octet data acquisition software v6.X or v4.X, locate the **IQOQ_Octet QKe_Quantitation_Repeat_v4-6.fmf** or the **IQOQ_Octet QK_Quantitation_Repeat_v4-6.fmf** method file, as appropriate for the system being qualified.*

1.5.1. On the IQOQ CD, go to SOFTWARE V6 folder.

*1.5.2. Go to the **QUALIFICATION METHOD FILES** folder.*

> *1.5.3. Click on the **IQOQ_Octet QKe_Quantitation_Repeat_v4-6.fmf** file or the **IQOQ_Octet QK_Quantitation_Repeat_v4-6.fmf** file, as appropriate for the system being qualified.*

and **Step 2.1** with the following:

> *2.1. Prepare a pre-wet microplate by adding 200 µL of Sample Diluent per well to all wells in column 2 of a 96-well microplate.*

and **Step 2.5** with the following:

> *2.5. Carefully lower the green biosensor rack on top of the pre-wet microplate in the biosensor tray holder to begin hydrating the biosensors in column 2.*

The steps described in **Section 3.4.3. Data Analysis Protocol** should be followed to analyze the test data.

Record the results in Table 3.3.

TABLE 3.3 MEASURED IgG CALIBRATOR CONCENTRATIONS IN 96-WELL MICROPLATE. IF CONC. CV VALUES ARE ≤ 10, THE QUANTITATION QUALIFICATION PASSES.

CONC. (µg/mL)	10	100	500
CONC. AVG			
CONC. CV			
PASS?	YES NO	YES NO	YES NO

If the quantitation qualification fails again, contact Fortebio Technical Support. Do not proceed to the Kinetics Qualification unless instructed by a Fortebio technical representative.

3.5. KINETICS QUALIFICATION

The Octet QK^e and Octet QK systems are qualified for use in kinetics assays by performing a baseline signal stability study on 96-well microplates using Fortebio's Streptavidin biosensors loaded with Biotin-Protein A.

NOTICE	*The Octet system must be powered on with the door closed for at least 3 hours before starting this test. Operation Qualification assays require ambient temperature ≤26°C in order to maintain default assay temperature of 30°C.*

3.5.1. OVERVIEW OF THE METHOD

1. A kinetics assay is set up on 96-well microplates.
2. Biotin-Protein A is first loaded on Streptavidin biosensors.
3. The baseline signal is monitored for stability over 1 hour in the sample microplate.
4. Assay data is analyzed for baseline signal drift. A PASS result is obtained when the drift is ≤ 0.1 nm/hr.

NOTICE	*The Kinetics Qualification should be performed only with reagents, biosensors and microplates provided with the Octet QK^e and Octet QK Validation and Testing kit.*

3.5.2. DATA ACQUISITION (EXPERIMENT SET UP AND RUN) PROTOCOL

1. Set up experiment in Octet software.

1.1. Ensure that the instrument has been turned on for at least 3 hours.

*1.2. From the IQOQ Validation and Testing kit, load the Octet QK^e and Octet QK **IQOQ CD** on the computer controlling the Octet system. If already loaded, proceed to Step 1.3.*

*1.3. Click on **File** in the menu options in Octet data acquisition software and choose **Open Method File...**.*

*1.4. If you are running Octet Data Acquisition Software v7.X, locate the **IQOQ_Octet QKe_QK_Kinetics_v7.fmf** method file.*

1.4.1. On the IQOQ CD, go to SOFTWARE V7 folder.

*1.4.2. Go to the **QUALIFICATION METHOD FILES** folder.*

*1.4.3. Click on the **IQOQ_Octet QKe_QK_Kinetics_v7.fmf** file.*

*1.5. If you are running Octet Data Acquisition Software v6.X or v4.X, locate the **IQOQ_Octet QKe_QK_Kinetics_v4-6.fmf** method file.*

1.5.1. On the IQOQ CD, go to SOFTWARE V6 folder.

*1.5.2. Go to the **QUALIFICATION METHOD FILES** folder.*

*1.5.3. Click on the **IQOQ_Octet QKe_QK_Kinetics_v4-6.fmf** file.*

*1.6. Click the **Open** button to load the method file.*

1.7. If you are running Octet Data Acquisition software v7.X, to enter Sensor lot number information:

*1.7.1. Click on **Tab 3, Sensor Assignment**.*

*1.7.2. In the table, enter the lot number under the **Lot Number** column. The lot number of the Streptavidin biosensors used in the experiment can be found on the biosensor tray pouch label.*

1.8. If you are running Octet Data Acquisition software v6.X or v4.X, to enter Sensor lot number information:

*1.8.1. Click on **Tab 5, Run Experiment**.*

*1.8.2. In the **Sensor lot number:** field, enter the lot number (Figure 3.11). The lot number of the Streptavidin biosensors used in the experiment can be found on the biosensor tray pouch label.*

*1.9. In the **Kinetics data repository:** field, enter the directory location where you prefer to save the qualification data files. It is recommended that the repository be located on a local drive.*

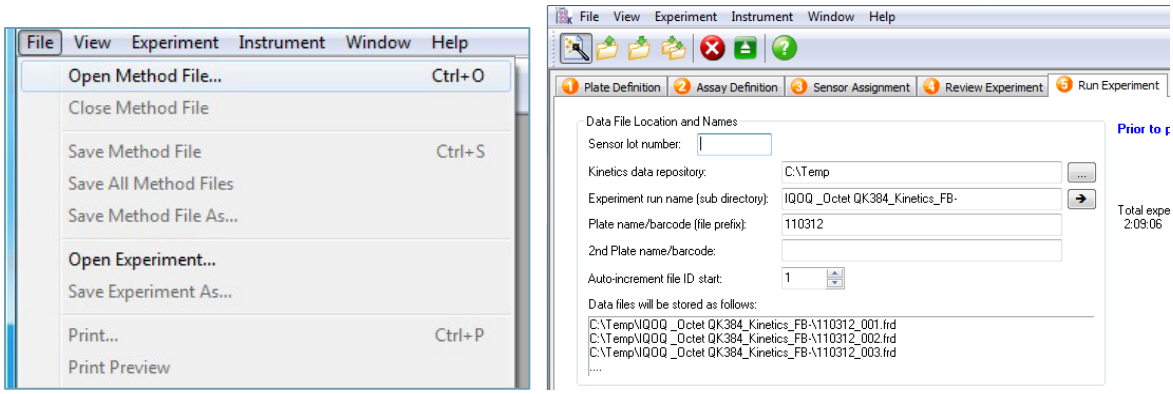


FIGURE 3.11. OCTET DATA ACQUISITION SOFTWARE ACTIONS TO SET UP KINETICS QUALIFICATION EXPERIMENT.

2. *Prepare biosensor tray.*

   2.1. *Prepare 20 mL of 1X Kinetics Buffer by diluting 2 mL of 10X Kinetics Buffer in 18 mL of PBS.*

   2.2. *Prepare a pre-wet microplate by adding 200 µL of 1X Kinetics Buffer per well to all wells in column 1 of a 96-well microplate.*

   2.3. *Remove the clear lid of the Streptavidin biosensor tray.*

   2.4. *Lift the green biosensor rack carefully out of the blue biosensor tray holder.*

   2.5. *Place the pre-wet plate inside the blue biosensor tray holder.*

   2.6. *Carefully lower the green biosensor rack on top of the pre-wet microplate in the biosensor tray holder to begin hydrating the biosensors in column 1.*

   2.7. *Load the entire ensemble, including the blue biosensor tray holder on to the biosensor tray location in the Octet system (Fig 3.2).*

3. *Prepare sample microplate.*

   3.1. *Dilute 100 µL of the Biotin-Protein A solution (250 µg/mL stock solution) into 1.9 mL of 1X Kinetics Buffer to make 2 mL of 12.5 µg/mL solution.*

   3.2. *Pipet 200 µL of the 1X Kinetics Buffer into wells in columns 1, and 3 of a 96-well microplate. Use Table 3.4 of this User Guide or the sample plate table in* ***Tab 1, Plate Definition*** *of method file in Octet software to determine sample locations. An illustration of Tab 1 is shown in Figure 3.12.*

   3.3. *Pipet 200 µL of Biotin- Protein A solution (12.5 µg/mL) into wells in column 2.*

3.4. Remove any bubbles that may be present in the microplate.

3.5. Load the sample plate in the sample plate location on the plate stage of the Octet system (Figure 3.2).

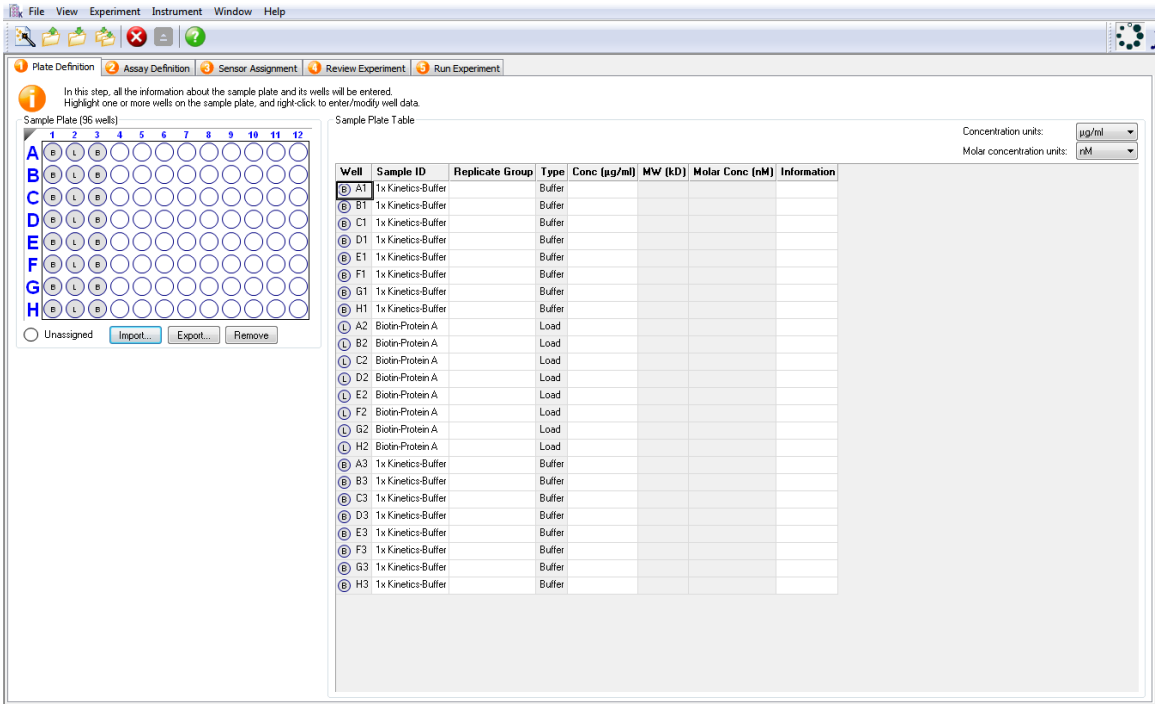


FIGURE 3.12. TAB 1, PLATE DEFINITION OF OCTET DATA ACQUISITION SOFTWARE SHOWS SAMPLE PLATE AND REAGENT PLATE MAPS.

TABLE 3.4 KINETICS ASSAY SAMPLE PLATE MAP.

	1	2	3	4	5	6	7	8	9	10	11	12
A	B	L	B									
B	B	L	B									
C	B	L	B									
D	B	L	B									
E	B	L	B									
F	B	L	B									
G	B	L	B									
H	B	L	B									

Sample Plate Map; L = Biotin-Protein A, B = 1X Kinetics Buffer

4. *Start the experiment.*

   4.1. *Ensure at least 10 minutes of hydration of the biosensors in the pre-wet microplate before starting the experiment.*

   4.2. *Go to **Tab 5, Run Experiment** in Octet data acquisition software.*

   4.3. *Press the **GO** button to start the experiment.*

   4.4. *The experiment should be complete in approximately 1 hr 20 min. After completion of the experiment, proceed to data analysis.*

3.5.3. DATA ANALYSIS PROTOCOL

1. *Load data into Octet data analysis software.*

   1.1. *To perform data analysis, open Octet data analysis software by double-clicking the analysis software icon or from the Start menu.*

   1.2. *In **Tab 1**, **Data Selection**, lower left-hand window, select the experiment folder created from the kinetics qualification experiment.*

   1.3. *Right-click the selection and choose **Load Folder** option (Figure 3.13). This action will populate the folder in the top left-hand side window under the **Kinetics** folder.*

   1.4. *Click on the folder name in the **Loaded Data** window. This action loads the experimental data into the data analysis software.*

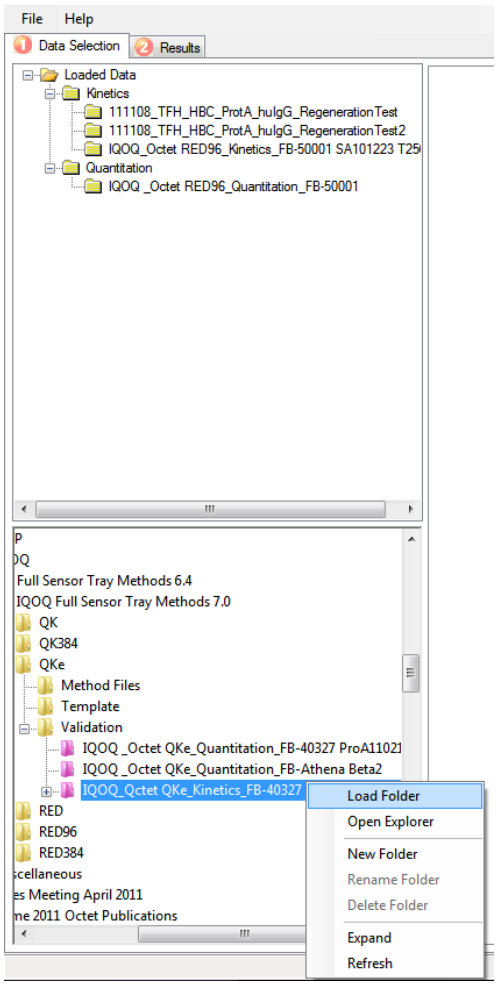


FIGURE 3.13. LOADING THE KINETICS QUALIFICATION DATA FOLDER IN OCTET DATA ANALYSIS SOFTWARE.

2. *Process data in Octet data analysis software.*

   2.1. *Click on the **Processing** tab.*

   2.2. *Click on **Save Raw Data** (Figure 3.14).*

   2.3. *In the pop-up window, choose the folder to save raw data in to.*

   2.4. *Press OK. This action saves the raw data in a file called **RawData.xls**.*

FIGURE 3.14. PROCESSING TAB OF OCTET DATA ANALYSIS SOFTWARE SHOWS AN EXAMPLE DATA SET FOR DRIFT TESTING.

3. Analyze data in Microsoft Excel software.

*3.1. Open the **RawData.xls** file in Microsoft Excel software. If a control window pops up asking for confirmation to open the file, such as in Figure 3.15, click on the **Yes** button.*

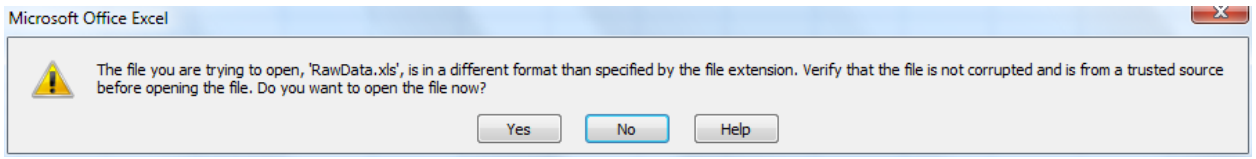
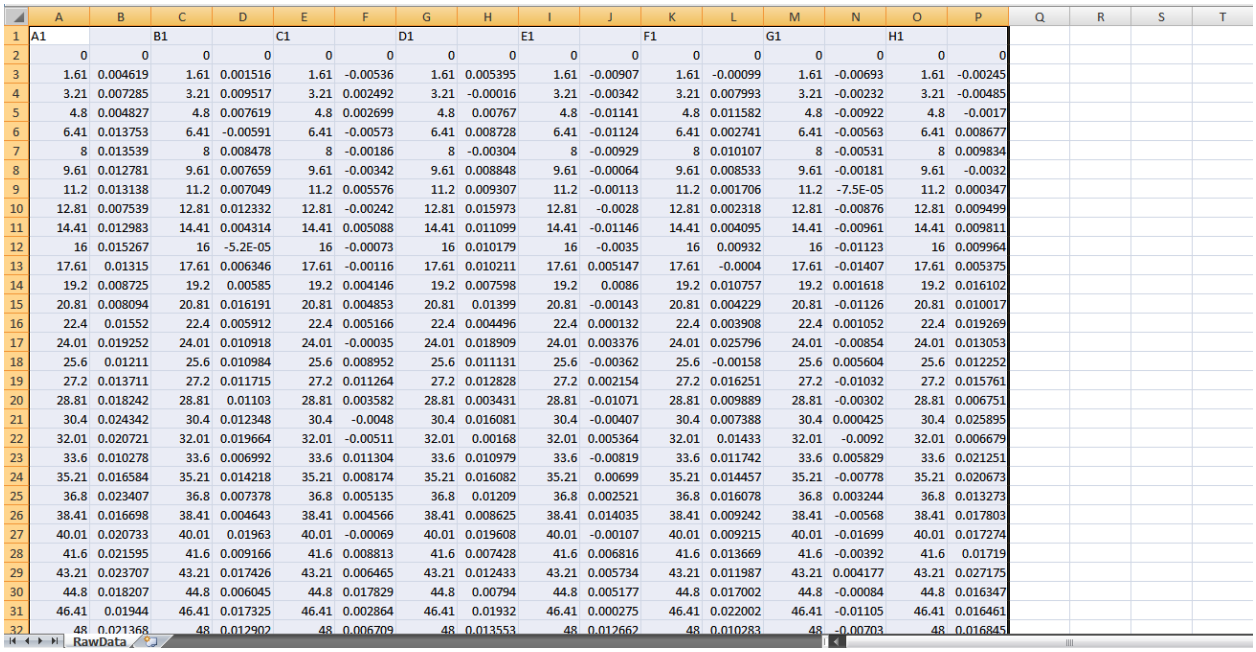


FIGURE 3.15. CLICK ON YES BUTTON TO OPEN 'RAWDATA.XLS' FILE.

*3.2. Click on the **Next** button(s) in the windows that pop up until clicking on the **Finish** button.*

3.3. Select all the data including the column headers (Figure 3.16).



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	A1		B1		C1		D1		E1		F1		G1		H1	
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	1.61	0.004619	1.61	0.001516	1.61	-0.00536	1.61	0.005395	1.61	-0.00907	1.61	-0.00099	1.61	-0.00693	1.61	-0.00245
4	3.21	0.007285	3.21	0.009517	3.21	0.002492	3.21	-0.00016	3.21	-0.00342	3.21	0.007993	3.21	-0.00232	3.21	-0.00485
5	4.8	0.004827	4.8	0.007619	4.8	0.002699	4.8	0.00767	4.8	-0.01141	4.8	0.011582	4.8	-0.00922	4.8	-0.0017
6	6.41	0.013753	6.41	-0.00591	6.41	-0.00573	6.41	0.008728	6.41	-0.01124	6.41	0.002741	6.41	-0.00563	6.41	0.008677
7	8	0.013539	8	0.008478	8	-0.00186	8	-0.00304	8	-0.00929	8	0.010107	8	-0.00531	8	0.009834
8	9.61	0.012781	9.61	0.007659	9.61	-0.00342	9.61	0.008848	9.61	-0.00064	9.61	0.008533	9.61	-0.00181	9.61	-0.0032
9	11.2	0.013138	11.2	0.007049	11.2	0.005576	11.2	0.009307	11.2	-0.00113	11.2	0.001706	11.2	-7.5E-05	11.2	0.000347
10	12.81	0.007539	12.81	0.012332	12.81	-0.00242	12.81	0.015973	12.81	-0.0028	12.81	0.002318	12.81	-0.00876	12.81	0.009499
11	14.41	0.012983	14.41	0.004314	14.41	0.005088	14.41	0.011099	14.41	-0.01146	14.41	0.004095	14.41	-0.00961	14.41	0.009811
12	16	0.015267	16	-5.2E-05	16	-0.00073	16	0.010179	16	-0.0035	16	0.00932	16	-0.01123	16	0.009964
13	17.61	0.01315	17.61	0.006346	17.61	-0.00116	17.61	0.010211	17.61	0.005147	17.61	-0.0004	17.61	-0.01407	17.61	0.005375
14	19.2	0.008725	19.2	0.00585	19.2	0.004146	19.2	0.007598	19.2	0.0086	19.2	0.010757	19.2	0.001618	19.2	0.016102
15	20.81	0.008094	20.81	0.016191	20.81	0.004853	20.81	0.01399	20.81	-0.00143	20.81	0.004229	20.81	-0.01126	20.81	0.010017
16	22.4	0.01552	22.4	0.005912	22.4	0.005166	22.4	0.004496	22.4	0.000132	22.4	0.003908	22.4	0.001052	22.4	0.019269
17	24.01	0.019252	24.01	0.010918	24.01	-0.00035	24.01	0.018909	24.01	0.003376	24.01	0.025796	24.01	-0.00854	24.01	0.013053
18	25.6	0.01211	25.6	0.010984	25.6	0.008952	25.6	0.011131	25.6	-0.00362	25.6	-0.00158	25.6	0.005604	25.6	0.012252
19	27.2	0.013711	27.2	0.011715	27.2	0.011264	27.2	0.012828	27.2	0.002154	27.2	0.016251	27.2	-0.01032	27.2	0.015761
20	28.81	0.018242	28.81	0.01103	28.81	0.003582	28.81	0.003431	28.81	-0.01071	28.81	0.009889	28.81	-0.00302	28.81	0.006751
21	30.4	0.024342	30.4	0.012348	30.4	-0.0048	30.4	0.016081	30.4	-0.00407	30.4	0.007388	30.4	0.000425	30.4	0.025895
22	32.01	0.020721	32.01	0.019664	32.01	-0.00511	32.01	0.00168	32.01	0.005364	32.01	0.01433	32.01	-0.0092	32.01	0.006679
23	33.6	0.010278	33.6	0.006992	33.6	0.011304	33.6	0.010979	33.6	-0.00819	33.6	0.011742	33.6	0.005829	33.6	0.021251
24	35.21	0.016584	35.21	0.014218	35.21	0.008174	35.21	0.016082	35.21	0.00699	35.21	0.014457	35.21	-0.00778	35.21	0.020673
25	36.8	0.023407	36.8	0.007378	36.8	0.005135	36.8	0.01209	36.8	0.002521	36.8	0.016078	36.8	0.003244	36.8	0.013273
26	38.41	0.016698	38.41	0.004643	38.41	0.004566	38.41	0.008625	38.41	0.014035	38.41	0.009242	38.41	-0.00568	38.41	0.017803
27	40.01	0.020733	40.01	0.01963	40.01	-0.00069	40.01	0.019608	40.01	-0.00107	40.01	0.009215	40.01	-0.01699	40.01	0.017274
28	41.6	0.021595	41.6	0.009166	41.6	0.008813	41.6	0.007428	41.6	0.006816	41.6	0.013669	41.6	-0.00392	41.6	0.01719
29	43.21	0.023707	43.21	0.017426	43.21	0.006465	43.21	0.012433	43.21	0.005734	43.21	0.011987	43.21	0.004177	43.21	0.027175
30	44.8	0.018207	44.8	0.006045	44.8	0.017829	44.8	0.00794	44.8	0.005177	44.8	0.017002	44.8	-0.00084	44.8	0.016347
31	46.41	0.01944	46.41	0.017325	46.41	0.002864	46.41	0.01932	46.41	0.000275	46.41	0.022002	46.41	-0.01105	46.41	0.016461
32	48	0.021368	48	0.012902	48	0.006709	48	0.013553	48	0.012662	48	0.010283	48	-0.00703	48	0.016845

RawData

FIGURE 3.16. SELECT ALL DATA INCLUDING THE COLUMN HEADERS IN RAWDATA.XLS FILE.

*3.4. Click on the **Copy** button to copy the selected data.*

*3.5. If you are running Octet Data Acquisition Software v7.X, locate the **IQOQ_Octet QKe_QK_Excel Calculations_v7.xlsx** excel file.*

3.5.1. On the IQOQ CD, go to SOFTWARE V7 folder.

*3.5.2. Click on the **IQOQ_Octet QKe_QK_Excel Calculations_v7.xlsx** file.*

*3.5.3. Go to the tab named **Paste Kinetics Raw data here**.*

*3.5.4. Paste the copied data into the worksheet starting at **cell A9** (Figure 3.17).*

*3.5.5. Save the **IQOQ_Octet QKe_QK_Excel Calculations_v7.xlsx** file to the local drive.*

*3.5.6. Go to the tab named **RESULTS SUMMARY** of the **IQOQ_Octet QKe_QK_Excel Calculations_v7.xlsx** file.*

*3.6. If you are running Octet Data Acquisition Software v6.X or v4.X, locate the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file that was previously used for quantitation qualification data analysis.*

*3.6.1. Go to the tab named **Paste Kinetics Raw data here**.*

*3.6.2. Paste the copied data into the worksheet starting at **cell A9** (Figure 3.17).*

*3.6.3. Save the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file to the local drive.*

*3.6.4. Go to the tab named **RESULTS SUMMARY** of the **IQOQ_Octet QKe_QK_Excel Calculations_v4-6.xlsx** file.*

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	slope	2.13215E-06		1.4763E-06		3.6E-06		1.56E-06		4.73E-06		2.19E-06		3.83E-06		2.53738E-06
2	intercept	1.485923937		1.47989124		1.472668		1.459795		1.455335		1.452815		1.462428		1.437984157
3	nm at 1sec	1.485926069		1.47989272		1.472672		1.459796		1.45534		1.452817		1.462432		1.437986694
4	nm at 3600sec	1.493599678		1.48520584		1.485614		1.465416		1.472362		1.460691		1.47622		1.44711873
5	baseline drift 1 hour	**0.00767**		**0.00531**		**0.01294**		**0.00562**		**0.01702**		**0.00787**		**0.01379**		**0.00913**
6		channel A		channel B		channel C		channel D		channel E		channel F		channel G		channel H
7	Copy all exported raw data below the blue line -> Go to Result Summary															
8																
9	A1		B1		C1		D1		E1		F1		G1		H1	
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	1.61	0.00461938	1.61	0.00151596	1.61	-0.00536	1.61	0.005395	1.61	-0.00907	1.61	-0.00099	1.61	-0.00693	1.61	-0.00245253
12	3.21	0.0072848	3.21	0.00951673	3.21	0.002492	3.21	-0.00016	3.21	-0.00342	3.21	0.007993	3.21	-0.00232	3.21	-0.00485416
13	4.8	0.00482692	4.8	0.00761907	4.8	0.002699	4.8	0.00767	4.8	-0.01141	4.8	0.011582	4.8	-0.00922	4.8	-0.00169802
14	6.41	0.0137529	6.41	-0.0059109	6.41	-0.00573	6.41	0.008728	6.41	-0.01124	6.41	0.002741	6.41	-0.00563	6.41	0.00867691
15	8	0.01353944	8	0.00847769	8	-0.00186	8	-0.00304	8	-0.00929	8	0.010107	8	-0.00531	8	0.00983442
16	9.61	0.01278083	9.61	0.00765912	9.61	-0.00342	9.61	0.008848	9.61	-0.00064	9.61	0.008533	9.61	-0.00181	9.61	-0.00320358
17	11.2	0.01313806	11.2	0.00704908	11.2	0.005576	11.2	0.009307	11.2	-0.00113	11.2	0.001706	11.2	-7.5E-05	11.2	0.00034697
18	12.81	0.00753864	12.81	0.01233156	12.81	-0.00242	12.81	0.015973	12.81	-0.0028	12.81	0.002318	12.81	-0.00876	12.81	0.0094991
19	14.41	0.01298332	14.41	0.00431437	14.41	0.005088	14.41	0.011099	14.41	-0.01146	14.41	0.004095	14.41	-0.00961	14.41	0.00981079
20	16	0.01526702	16	-0.00005168	16	-0.00073	16	0.010179	16	-0.0035	16	0.00932	16	-0.01123	16	0.00996372
21	17.61	0.0131495	17.61	0.00634642	17.61	-0.00116	17.61	0.010211	17.61	0.005147	17.61	-0.0004	17.61	-0.01407	17.61	0.00537548
22	19.2	0.00872486	19.2	0.00585037	19.2	0.004146	19.2	0.007598	19.2	0.0086	19.2	0.010757	19.2	0.001618	19.2	0.01610225
23	20.81	0.00809441	20.81	0.0161913	20.81	0.004853	20.81	0.01399	20.81	-0.00143	20.81	0.004229	20.81	-0.01126	20.81	0.01001699
24	22.4	0.01551972	22.4	0.00591239	22.4	0.005166	22.4	0.004496	22.4	0.000132	22.4	0.003908	22.4	0.001052	22.4	0.0192694
25	24.01	0.01925205	24.01	0.01091816	24.01	-0.00035	24.01	0.018909	24.01	0.003376	24.01	0.025796	24.01	-0.00854	24.01	0.01305254
26	25.6	0.01211012	25.6	0.01098371	25.6	0.008952	25.6	0.011131	25.6	-0.00362	25.6	-0.00158	25.6	0.005604	25.6	0.01225229

FIGURE 3.17. PASTE COPIED DATA AT CELL A9 IN THE PASTE KINETICS DATA HERE TAB.

4. Evaluate data and record results.

*4.1. In the table titled **Octet QK/QKe – Kinetics Qualification Summary**, the measured signal drift values are automatically populated for all 8 channels of the Octet system. An indication of **Pass** or **Fail** is also shown in the table for each channel. Record the drift values for all 8 channels in Table 3.5.*

NOTICE	*The signal drift values should be ≤ 0.1 nm/hour for all 8 channels monitored in order for the Octet system to pass kinetics qualification.*

*4.2. Circle **Pass** or **Fail** as appropriate for each channel in Table 3.5. The kinetics qualification passes only when all 8 channels pass the test.*

*4.3. The RMS noise data calculated and reported in the **Octet QK/QK^e – Kinetics Qualification Summary** table is not a specification for kinetics qualification of the Octet system. No action is needed on this data.*

*4.4. Print all data in the **Rawdata** tab and the **Results Summary** of the **RawData.xls** file.*

4.5. The person performing the qualification test should sign and date the document.

4.6. Attach the document to the Octet QK^e and Octet QK IQOQ User Manual.

TABLE 3.5. BASELINE DRIFT. THE OCTET INSTRUMENT MUST PASS DRIFT TEST ON ALL 8 BIOSENSORS TO PASS OPERATION QUALIFICATION.

CHANNEL	BASELINE CHANGE (DRIFT)		PASS
	MEASURED	SPECIFICATION	
A1		≤ 0.1 nm/hr	YES / NO
B1			
C1			
D1			
E1			
F1			
G1			
H1			

3.5.4. REPEAT KINETICS QUALIFICATION

If the Octet system passed kinetics qualification, a repeat test is not needed. You have completed the operational qualification of the system. In the event of a failed kinetics qualification, consult with a Fortebio Technical Support representative to determine if a repeat test is required. The Octet QK^e and Octet QK IQOQ Validation and Testing kit contains enough biosensors, reagents and microplates to perform a repeat test.

Do not reuse any reagents from the microplates. Discard the used microplates and reagents, and take fresh microplates from the IQOQ Validation and Testing kit for the repeat test.

NOTICE	*Do not reuse any reagents from the microplates. Discard the used microplates and reagents, and take fresh microplates from the IQOQ Validation and Testing kit for the repeat test.*

Since the first column of biosensors from the Streptavidin biosensor tray have been used, the second column of biosensors should be used in the repeat test. Follow the protocol described in **Section 3.5.2. Data Acquisition (Experiment Set Up and Run) Protocol**, with the exception of replacing **Step 1.4** and **1.5.** with the following:

*1.4. If you are running Octet Data Acquisition Software v7.X, locate the **IQOQ_Octet QKe_QK_Kinetics_Repeat_v7.fmf** method file.*

1.4.1. On the IQOQ CD, go to SOFTWARE V7 folder.

*1.4.2. **Go to the METHOD FILES FOR REPEAT EXPERIMENT** folder.*

*1.4.3. **Click on the IQOQ_Octet QKe_QK_Kinetics_Repeat_v7.fmf file.***

*1.5. If you are running Octet Data Acquisition Software v6.X or v4.X, locate the **IQOQ_Octet QKe_QK_Kinetics_Repeat_v4-6.fmf** method file.*

1.5.1. On the IQOQ CD, go to SOFTWARE V6 folder.

*1.5.2. Go to the **METHOD FILES FOR REPEAT EXPERIMENT** folder.*

*1.5.3. Click on the **IQOQ_Octet QKe_QK_Kinetics_Repeat_v4-6.**fmf file.*

and **Step 2.2.** with the following:

2.2. Prepare a pre-wet microplate by adding 200 µL of 1X Kinetics Buffer per well to all wells in column 2 of a 96-well microplate.

.

and Step 2.6 with the following:

2.6. Carefully lower the green biosensor rack on top of the pre-wet microplate in the biosensor tray holder to begin hydrating the biosensors in column 2.

The steps described in **Section 3.5.3. Data Analysis Protocol** should be followed to analyze the test data.

Record the results in Table 3.6.

TABLE 3.6. BASELINE DRIFT. THE OCTET INSTRUMENT MUST PASS DRIFT TEST ON ALL 8 BIOSENSORS TO PASS OPERATION QUALIFICATION.

CHANNEL	BASELINE CHANGE (DRIFT)		PASS
	MEASURED	SPECIFICATION	
A3		≤ 0.1 nm/hr	YES NO
B3			
C3			
D3			
E3			
F3			
G3			
H3			

If the kinetics qualification fails again, contact Fortebio Technical Support.

3.6. COMMENTS (PAGE INTENTIONALLY LEFT BLANK)

3.7. OPERATION QUALIFICATION SIGN OFF

All steps required for the Octet system operation qualification have been completed, documented and reviewed. All discrepancies noted during operation qualification have been satisfactorily resolved. The Octet system is qualified for use.

AUTHORIZED FORTEBIO REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE:

AUTHORIZED CUSTOMER REPRESENTATIVE

SIGNATURE:
NAME:
DATE: