

PQ ELITE MGB® Kit

for evaluation of ELITE InGenius® and ELITE BeGenius®
Code: RTKPQ



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This document is available only in English.

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A. Intended use

The PQ ELITE MGB® Kit (code RTKPQ) is a Real-Time PCR assay used for Performance Qualification (PQ) of ELITE InGenius and ELITE BeGenius instruments. How to use the product and perform PQ tests is extensively described in the documents IO11,18 "ELITech ELITE InGenius Performance Qualification", IO11,22 "ELITech ELITE BeGenius Performance Qualification", MOD11,26 "InGenius Performance Qualification Report" and MOD11,32 "BeGenius Performance Qualification Report".

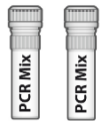
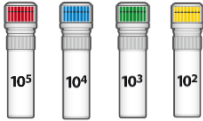
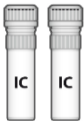

B. References

- › INT030: ELITE InGenius® User Manual
- › INT030_SM: ELITE InGenius® Service Manual
- › IO11,18: ELITech ELITE InGenius® Performance Qualification
- › MOD11,26: ELITE InGenius® Qualification Report
- › INT040-US: ELITE BeGenius® Operator Manual
- › INT040-SM: ELITE BeGenius® Service Manual
- › IO11,22: ELITech ELITE BeGenius® Performance Qualification
- › MOD11,32: ELITE BeGenius® Qualification Report
- › SCH mINT032SP200_en: ELITE InGenius® SP200 Instruction for Use (IFU)
- › SCH mINT032CS_en: ELITE InGenius® SP200 Consumable Set IFU
- › SCH mINT035PCR_en: ELITE InGenius® PCR Cassette IFU
- › SCH mF2102-000_en: ELITE InGenius® Waste Box IFU

C. Amplified sequence

Target	Gene	Fluorophore
Internal Control	CMV MIEA gene (exon 4 region)	FAM
	Human beta Globin gene	AP525

D. PQ ELITE MGB® Kit content

PQ PCR Mix	PQ Q PCR Standard	PQ Internal Control	PQ Positive Control
			
Ready-to-use PCR Mix	Ready-to-use 4 levels: 10 ⁵ , 10 ⁴ , 10 ³ , 10 ²	Ready-to-use IC	Ready-to-use PC
Volume for Kit: 2 tubes of 540 µL	Volume for Kit :1 set of 4 tubes of 200 µL	Volume for Kit:2 tubes of 200 µL	Volume for Kit:1 tube of 160 µL
N° of freeze-thaw cycles: 7	N° of freeze-thaw cycles: 4	N° of freeze-thaw cycles:12	N° of freeze-thaw cycles: 4

The reagents supplied allow to perform 4 PQ Test with ELITE InGenius instrument or 2 PQ Test with ELITE BeGenius instrument.

Maximum shelf-life: **24 months** Storage Temperature: **-20 °C**

E. Materials and Equipments required not provided in the kit

ELITE InGenius instrument: INT030
 ELITE BeGenius instrument: INT040
 ELITE InGenius SP200 Extraction Cartridge: INT032SP200
 ELITE InGenius PCR Cassette: INT035PCR
 1000 µL Filter tips Tecan: 301226095
 ELITE InGenius Waste Box: F2102-000
 300 µL Filter Tips Axygen : TF-350-L-R-S (for INT030)
 Pipettes and Micropipettes, Vortex Mixer Microcentrifuge (13.000 RPM)
 Assay Protocols: Qualification Assay Calibrators, Qualification Assay Positive Control, Qualification Assay Negative Control and Qualification Assay for ELITE InGenius and ELITE BeGenius

F. ELITe InGenius/BeGenius protocol

› Sample volume	200 µL
› CPE volume	10 µL
› Total elution volume	100 µL
› PCR elution input volume	20 µL
› PCR Mix volume	20 µL

G. ELITe InGenius procedure

Before analysis

1. Switch on ELITe InGenius Identification with username and password. Select the mode "Open"
2. Uninstall previous version of the Qualification Assay Protocols if different from the Assay Protocols revision in use (to uninstall Assay Protocols, calibration curves, control charts, reagents and templated associated have to be removed).
3. If not already installed, from "Service Maintenance" select "System Settings", insert a "USB Flash Drive" containing the latest release of the "Qualification Assay" and select "Program/Edit Assay", selecting the "Flash Drive" button to import the Assay Protocols
4. Thaw one tube for each component of the PQ ELITe MGB® Kit. Vortex gently and spin down 5 sec.
5. Setup the instrument following indications in the table below:

	Position	Track	Consumables	Reagent	Code	
Main Area	PCR rack	1 to 12	PCR cassettes		INT035PCR	
	Extraction rack	7 to 12	Extraction cassettes		INT032SP200	
	Elution rack	1			10 ² PQ Standard	STDPO-2
		2			10 ³ PQ Standard	STDPO-3
		3			10 ⁴ PQ Standard	STDPO-4
		4			10 ⁵ PQ Standard	STDPO-5
		5			PQ Positive Control	CTRPQ
		6	0.5 mL eluate tube		Full with Nuclease Free water greater than or equal to 40 µl	INT032CS
	7 to 12			Empty	INT032CS	
	Extraction tip rack	7 to 12	Extraction tip cassettes		INT032CS	
Extraction tube rack	7 to 12	Extraction tubes	200 µl of Nuclease Free water	INT032CS		
User Area	Inventory reagent manager area/Cooling block			PQ PCR Mix	RTSPQ	
				PQ Internal Control	CPEPQ	
	Filter Tip racks		Filter Tips 300		Axygen TF-350-L-R-S	
	Waste bin		Waste box		F2102-000	

NB: Remove all caps from the tubes.

Run Setup

1. Select "Perform Run" on the touch screen
2. Verify the extraction volumes: Input: "200 µL", Elute: "100 µL"
3. Select the "Assay Protocol" of interest: <ul style="list-style-type: none"> › Tracks 1 to 4: Qualification Assay Calibrators, › Track 5: Qualification Assay Positive Control, › Track 6: Qualification Assay Negative Control, › Lanes 7 to 12: Qualification Assay.
4. For tracks 7 to 12: <ul style="list-style-type: none"> › select the mode "Extract + PCR". › set the sample position: "Extraction tube". › Input a SampleID of your choose
5. Progress through the confirmation screens ensuring that all consumables and reagents are in their proper places.
6. Close the door. Start the run.
7. When the run is finished, save the pdf Calibration Report, the pdf track report of all tracks and the Raw Data of all tracks.
8. Fill out the MOD11,26

H. ELITE BeGenius procedure

Before analysis

1. Switch on ELITE BeGenius Identification with username and password. Select the mode "Open"
2. Uninstall previous version of the Qualification Assay Protocols if different from the Assay Protocols revision in use (to uninstall Assay Protocols, calibration curves, control charts, reagents and templated associated have to be removed).
3. If not already installed, from "Service Maintenance" select "System Settings", insert a "USB Flash Drive" containing the latest release of the "Qualification Assay" and select "Program/Edit Assay", selecting the "Flash Drive" button to import the Assay Protocols
4. Thaw one tube for each component of the PQ ELITE MGB® Kit. Vortex gently and spin down 5 sec.
5. Setup the instrument following indications in the table below:

	Position	Track	Consumables	Reagent	Code	
Main Area	PCR rack	1 to 24	PCR cassettes		INT035PCR	
	Extraction rack	1 to 12	Extraction cassettes		INT032SP200	
			Extraction tip cassettes		INT032CS	
			Extraction tubes		INT032CS	
	Tip rack		1000 µL Filter tips Tecan		30126095	
Waste bin		Waste box		F2102-000		
Cool Block	Lane 5			Empty		
	Lane 4			Empty		
	Lane 3	1 to 12	0.5 mL eluate tube	Empty	INT032CS	
	Lane 2	1			PQ PCR Mix	RTSPQ
		2			PQ Internal Control	CTRPQ
		3			10 ² PQ Standard	STDQP-2
		4			10 ³ PQ Standard	STDQP-3
		5			10 ⁴ PQ Standard	STDQP-4
		6			10 ⁵ PQ Standard	STDQP-5
		7	0.5 mL eluate tube		Fill with Nuclease Free water greater than or equal to 40 µL	INT032CS
	8			PQ Positive Control	CTRPQ	
Lane 1			Empty			

NB: Remove all caps from the tubes.

Run Setup

1. Select "Perform Run" on the touch screen
2. Chose the Protocol "Extract+PCR"
3. When the GUI indicates to insert rack in lanes 5, click "Abort" and check all the "Extr tube" boxes for the 12 tracks. <ul style="list-style-type: none"> ➤ Select the "Sample ID" field and enter the Sample ID: the corresponding dot in the E1 lane turns on blue. ➤ Select "End loading primary samples" to avoid the setup of the second extraction.
4. In Lane 5 Assay Setting, ensure that extraction input volume is 200 µL and Elution Volume is 100 µL. <ul style="list-style-type: none"> ➤ Select all positions and associate to each sample the Qualification Assay.
5. Skip the Print Labels passage clicking on "Next" button.
6. Place 12 empty 0.5 mL eluate tubes on Reagent Rack in lane 3 and, for all the 12 tracks, select the "Entered manually" option in the "Status" column.
7. Skip the following passages until the GUI request to insert a Reagent Rack in Lane 2.
8. Place the following reagents in the positions of Reagent rack (see below) and insert it in Lane 2 with barcodes oriented in order to be read by the barcode reader: <ul style="list-style-type: none"> ➤ PQ PCR Mix in position 1 ➤ PQ Internal Control in position 2 ➤ 1° calibrator in position 3 ➤ 2° calibrator in position 4 ➤ 3° calibrator in position 5 ➤ 4° calibrator in position 6 ➤ Negative Control in position 7 ➤ PQ Positive Control in position 8
9. In Assay setting screen, assign the Assay protocol how described: <ul style="list-style-type: none"> ➤ to calibrators the Qualification Calibrators Assay ➤ to Negative Control the Qualification Assay Negative Control ➤ to Positive Control the Qualification Assay Positive Control.
10. Abort the reading of rack in Lane 1
11. Progress through the confirmation screens ensuring that all consumables and reagents are in their proper places.
12. Close the door. Start the run.
13. When the run is finished, save the pdf Calibration Report, the pdf track report of all tracks and the Raw Data of all tracks.
14. Fill out the MOD11,32.

I. ELITe InGenius/BeGenius Acceptance Criteria

The criteria of the PQ test are batch specific and set out in the registration documents MOD11,26 “InGenius Performance Qualification Report” and MOD11,32 “BeGenius Performance Qualification Report”.

The documents updated with the criteria of the new released batches of PQ ELITe MGB® Kit are available on the ELITeBoard on sections “_ELITe BeGenius/_MOD11,32 PQ Performance Qualification Report” and “_ELITe InGenius/_MOD11,26 PQ Performance Qualification Report”.