### **ELITechGroup ELITe InGenius® Quick Reference Guide**





# ELITE InGenius

ELITe InGenius® Quick Reference Guide for SW v 1.3.0.16

EMD InGenius QG 490-202000EN

**Revision 02** 

#### **DISCLAIMER**

This Quick Reference Guide is a simplified version of the official instruction for use and the intended use is to provide an overview of the most frequently used functions of the ELITechGroup ELITe InGenius<sup>®</sup>. The ELITe InGenius may only be used by authorized and trained personnel. This guide cannot be considered as a substitute for official trainings supported by ELITechGroup and official operator manual ELITe InGenius Operator Manual; therefore, please refer to the complete operator manual before using the instrument.

This Quick Reference Guide is not intended to provide a complete overview of all functions, safety measures, precautions, cautions and restrictions of the analyzer. These are covered in the ELITe InGenius Operator Manual. For reagents and consumables, please consult the related Instructions for Use. This Quick Reference Guide is compatible with SW V1.3.0.16

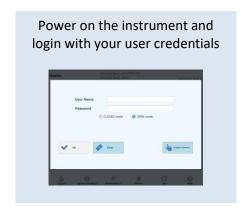
For additional help with troubleshooting of instrument problems please contact your local ELITechGroup ELITe InGenius® distributor support personnel, or ELITechGroup Technical Service and Support Center. Please visit our website at <a href="https://www.elitechgroup.com">www.elitechgroup.com</a> for more information.

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### **ELITechGroup ELITe InGenius® Setup Procedures**

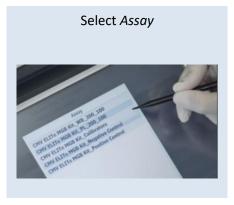
#### **Procedure 1 - Complete Run: Extraction + PCR Amplification**













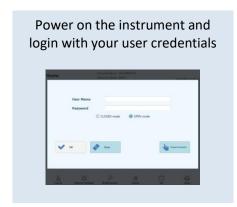






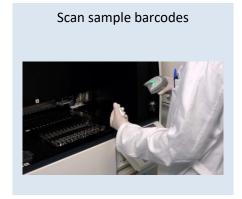
### **ELITechGroup ELITe InGenius® Setup Procedures**

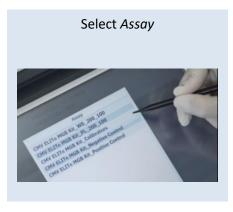
#### **Procedure 2 - PCR Amplification Only**

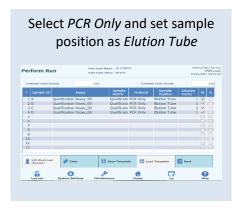


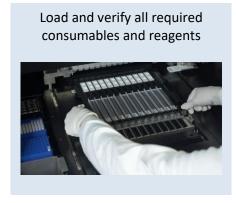


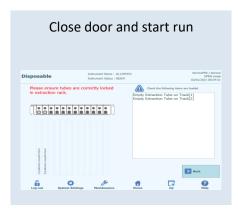








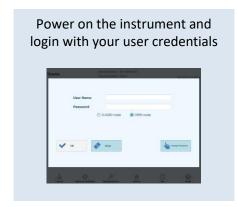






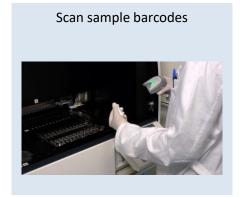
### **ELITechGroup ELITe InGenius® Setup Procedures**

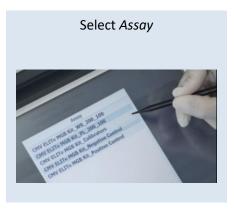
#### **Procedure 3 - Extraction Only**

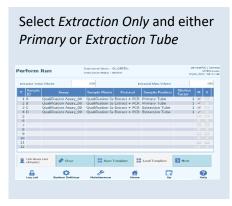


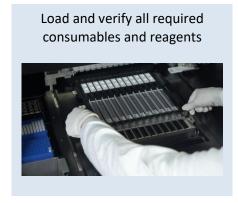




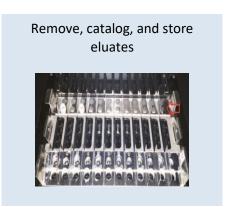






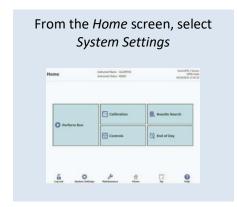






### **ELITechGroup ELITe InGenius® Restart Procedures**

#### Procedure 1 – System Monitor Method



















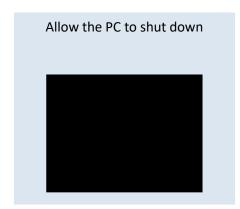
### **ELITechGroup ELITe InGenius® Restart Procedures**

#### Procedure 2 – Shutdown Method



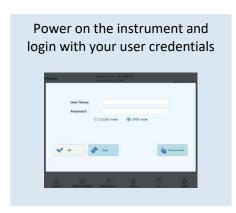














### **ELITechGroup ELITe InGenius® Log File Collection**

#### **Collecting Log Files**



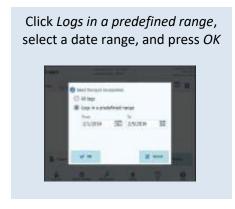
















### **ELITechGroup ELITe InGenius® Database Backup**

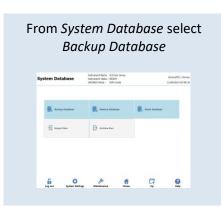
#### **Backing up the Database**











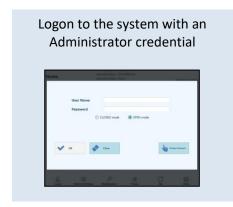






### **ELITechGroup ELITe InGenius® User Account Creation**

#### **Create a New User Account**













### **ELITechGroup ELITe InGenius® Protocol Upload**

#### **Uploading a Protocol**















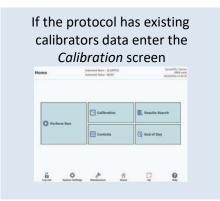




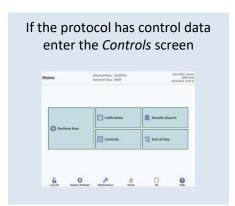
### **ELITechGroup ELITe InGenius® Protocol Deletion**

#### **Deleting a Protocol from the System**

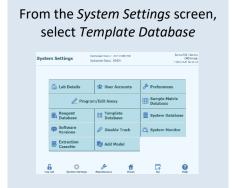












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### **ELITechGroup ELITe InGenius® Protocol Deletion (continued)**

#### **Deleting a Protocol from the System (continued)**

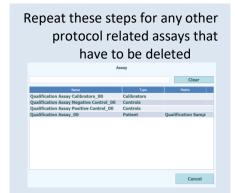












## **ELITechGroup ELITe InGenius® Common Error Codes**

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#### **Axis system errors**

Error Code	Error Description	Possible Cause	Suggested Resolution
2002	Z Bottom sensor error. Axis:" "	Axis impeded by foreign object, misplaced rack, or consumable	Follow proper shutdown procedure and restart system
2003	Hardware endlimit error.Axis " "	Axis impeded by foreign object, misplaced rack, or consumable	Follow proper shutdown procedure and manually move axis to free impediment and restart system
2004	Software endlimit error. Axis:" "	The motor tried to move to the position exceeding to the Pulse set in Maximum/ Minimum of Fisics.ini.	Follow proper shutdown procedure and manually move affected axis to middle of range of motion and restart system
2005	Interlock error. "Axis"	Door interlock is not in closed position	See error under "Door lock failures"
2006	Initialize Motor error. " "	Motor Control SwLimit and EndLimit were detected during Org return.	Follow proper shutdown procedure and manually move affected axis to middle of range of motion and restart system  Service personnel only: Enter maintenance software and return affected axis to origin, and then initialize system
2506	Motor out-of-step error Axis:" "	Axis impeded by foreign object, misplaced rack, or consumable	Follow proper shutdown procedure and manually move axis to free impediment reset consumables and restart system

## **ELITechGroup ELITe InGenius® Common Error Codes**

### **Reagents and consumables**

Error Code	Error Description	Possible Cause	Suggested Resolution
	Failed to aspirate specified volume	Insufficient volume of monoreagent master mix for the specified track number	Repeat testing ensuring there is sufficient monoreagent present
20008	of Monoreagent.[Track#]	Insufficient volume of monoreagent master mix for the specified track number  Single nozzle pipette error  Missing tip cassette, or tip  12 nozzle pipette error  PCR Cap not in place in PCR Cassette  Check cion!  uch.)  DZ Axis malfunction  Internal control solution not  Repeat testing ensuring there is sufficient monoreagent present suffi	
20013	Failed to pickup piercing tip (PP75).[Track#] Confirm piercing tips	Missing tip cassette, or tip	
in	in tip rack. (Caution! Heat Block is hot. Do not touch.)	12 nozzle pipette error	
20027	No PCR cap found.[Track#] Check PCR cap(s) placement. (Caution!	1	another PCR cassette. Note: remove the black seal from front to back to avoid the Cap
	Heat Block is hot. Do not touch.)	I D7 Axis maltunction	
20034		completely thawed before	complete thawing of the internal
	Clogging during IC aspiration.[Track#]		I
		Single nozzle pipette error	

### Reagents and consumables (continued)

Error Code	Error Description	Possible Cause	Suggested Resolution
		Insufficient volume of eluate for the specified track number	Repeat testing ensuring there is sufficient eluate present in the tube
		Instrument not level	Schedule service visit to investigate root cause
20039	Failed to aspirate specified volume of eluate.[Track#]	Extraction failure yielded poor quality eluate	Schedule service visit to investigate root cause
		Consumable tip failure	Schedule service visit to investigate root cause
		Single nozzle pipette error	Schedule service visit to investigate root cause
		Insufficient volume of eluate for the specified track number	Repeat testing ensuring there is sufficient eluate present in the tube
		Instrument not level	Schedule service visit to investigate root cause
20042	Failed to aspirate eluate.[Track#]	Extraction failure yielded poor quality eluate	Schedule service visit to investigate root cause
		Consumable tip failure	Schedule service visit to investigate root cause
		Single nozzle pipette error	Schedule service visit to investigate root cause
20053	Unnecessary PP75 tip found.[Track#] Remove from PP75 tip holder. (Caution! Heat Block is hot. Do not touch.)	Tip cassette in a track not selected to run	Remove tip cassette from identified track

#### Reagents and consumables (continued)

		Tube absent in the Elution tube position	Place the tube into the elution tube rack containing the eluate
20055	No eluate found.[Track#] Set eluate(s). (Caution! Heat Block is hot. Do not touch.)	Consumable tip failure	Schedule service visit to investigate root cause
		Single nozzle pipette error	Schedule service visit to investigate root cause
20070	Piercing tip (PP75) dropped unexpectedly.[Track#] Remove the	Piercing tip not seated properly on 12 nozzle pipette	Remove loose piercing tip and continue run
20070	loose piercing tip from the stage. (Caution! Heat Block is hot. Do not touch.)	12 nozzle pipette error	Schedule service visit to investigate root cause
20084	There is a possibility that there is no elution tube of following tracks.{0}	No elution loaded Wrong size elution loaded	Load elution tube Load correct tube size
		12 nozzle misaligned 12 nozzle pressure sensor issue	12 nozzle teaching Verify or replace pcb

#### **Run Setup**

Warning Code	Error Description	Possible Cause	Suggested Resolution
00-0200	To do this, you will need to discard data in run setup screen	Information entered into run setup screen, then attempting to edit assay or access controls or calibrators	Proceeding will cause data in run setup screen to be lost
11-0800	Not allowed to setup a run with multiple instances of calibrators or controls	Multiple calibrators or controls programmed in run setup	Correct run setup error and retry
12-0102	Please enter sample IDs for all Patient Assays.[Track#]	Sample ID not entered	Enter sample ID for indicated track
12-3001	It is not possible to run a PCR only control with an E+P calibration curve	Run setup was attempted that violates rules	Correct run setup error and retry

**Reagents and consumables (continued)** 

12-3003	It is not possible to run a E+P control with a PCR only calibration curve	Run setup was attempted that violates rules	Correct run setup error and retry
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#### **Door lock failure**

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
	Interlock error. "Axis"	Door interlock is not in closed position	Close door properly and press retry button
2005	interiock error. Axis	Door interlock switch has failed	Schedule service visit to investigate root cause
	Interlock error. "Axis" and door is open during run	Door interlock was not in closed position when run was started and only one side was latched	Follow proper shutdown procedure and re-initialize instrument, run must be restarted
00-0020	Door lock failed	Door not shut properly	Close door properly and press lock retry button
		Door lock not properly aligned	Schedule service visit to investigate root cause
00-0021	Door unlock failed	Door is pressed against latch mechanism	Push in slightly on door to release latches

### **Barcode reading failure**

Warning Code	Error Description	Possible Cause	Suggested Resolution
12-0001 Barcode read error occurred Please re-scan the barcode	Missing consumable	Ensure correct consumable placement	
		se Misplaced consumable Ensure correct consumable placement	Ensure correct consumable placement
		Scanning position error	Schedule service visit to investigate root cause

#### **Software - User access & Passwords**

Warning Code	Error Description	Possible Cause	Suggested Resolution
06-0303	Your account has been locked. Please contact your system administrator.	Too many attempted logins (3 wrong attempt)	Login as administrator and unlock the account (System Settings screen > User Accounts)
06-0306	User Name not recognized	Mistyped user name	Correct user name and ensure correct case
06-0307	Password not recognized	Wrong password entered	Retry password entry
06-0309	Password must be at least 8 characters	Password is not 8 characters or longer	Retry password entry
06-0311	Invalid Login Attempt : "user name"	Mistyped user name	Correct user name and ensure correct case
06-0312	Invalid Password Entered : "user name"	Incorrect password entered	Enter correct password for user name
06-0402	Current password cannot be used as a new password	Attempted to use current password as new password	Choose a different password and retry
06-0404	Unable to change password - current password not recognized : "user name"	correct current password not entered	Enter correct password for user name
18-0205	Password and confirmation should be the same	Both passwords do not match	Ensure both passwords match and retry
18-0206	User name must be at least 8 characters	User name is not 8 characters or longer	Add additional characters to user name
08-0119	Lot number must be at least one character long	Lot number was not entered correctly	Enter a properly formatted lot number
08-0135	Control fluid will expire soon YYYY/MM/DD	Expiration value for control is approaching	Run control(s) soon

#### **Controls & Calibrators**

Warning Code	Error Description	Possible Cause	Suggested Resolution
10-0103	"Control set" Cannot remove Control Set: It is required by one or more assays in the database	Message to warn control set is associated with assays in the database	Control set data can be deleted, but the control set cannot be deleted until the assay is deleted
11-0002	No valid control data is available for Assay[Assay Name]	Control(s) has not yet been completed or approved	Run and approve control(s) before running samples or concurrently with samples
11-0004	No valid calibration curve and control data is available for Assay[Assay Name].	Calibrators and Control(s) have not yet been completed or approved	Run and approve calibrators and control(s) before or concurrently with samples
11-0701	No Calibration curves exist for this assay	Calibration curve has not yet been completed or approved	Run and approve calibrators before running samples or concurrently with samples
11-0703	No Valid Controls exist for this assay - Admin approval will be needed to start the run	Control(s) has not yet been completed	Administrator login needed to start run
11-0705	Calibration and Controls have expired for this assay - Admin approval will be needed to start the run	Calibrators and Control(s) have expired	Administrator login needed to start run
11-0707	No Approved Calibration exists for this assay - Admin approval will be needed to start the run	Calibration curve has not yet been completed	Administrator login needed to start run
11-0710	No Calibration curves exist for this assay	Calibration curve has not yet been completed	Run calibrators before running samples or concurrently with samples
11-0712	No Approved Calibration exists for this assay - Admin approval will be needed to start the run	Calibration curve has not yet been completed	Administrator login needed to start run
11-0713	Controls have expired for this assay - Admin approval will be needed to start the run "Assay Name"	Control(s) have expired	Administrator login needed to start run
11-0714	No Valid Controls exist for this assay - Admin approval will be needed to start the run	Control(s) has not yet been completed	Administrator login needed to start run

### **Controls and Calibrators (continued)**

Warning Code	Error Description	Possible Cause	Suggested Resolution
12-2301	Can't find a valid CALIBRATOR/CONTROL for: Assay:"assay name" Monoreagent Lot Number:######	Control(s) and/or calibrators (as specified in the warning) have not yet been completed	Run control(s) and/or calibrators (as specified in the warning) before running samples or concurrently with samples
12-2302	Can't find a valid CONTROL for: Assay:"assay name" Monoreagent Lot Number:######	Mistyped Lot number of the monoreagent batch associated to a valid calibrators and/or controls (common error the use of the letter "O" instead of the zero "O")	Check and correct the typos in the inventory manager "Lot number"
12-2303	Can't find a valid CALIBRATOR for: Assay: "assay name" Monoreagent Lot Number:######		

### **Results approval**

Warning Code	Error Description	Possible Cause	Suggested Resolution
14-0001	Invalid results cannot be approved Track=#	Results do not meet criteria prescribed during assay development	Review track report for affected track for criteria that is not acceptable
14-0002	Please approve Calibrator/Control results in the Calibration/Control screen - Track=#	Calibrator or Control result not yet approved	Approve Calibrator or Control

#### Reminders

Warning Code	Error Description	Possible Cause	Suggested Resolution
16-0301	Instrument <serial number=""> 1. million (1.000.000) of Optical Fiber Cable approaching</serial>	Optic fiber cycle count has reached 1. million (1.000.000)	Schedule annual service visit to replace fibers
16-0302	Instrument <serial number=""> MM/DD/YYYY lifetime expired on HEPA Filter</serial>	HEPA filter expiration value reached	Schedule annual service visit, or if erroneous reset HEPA Reminder

### **Assay protocols Configuration**

Warning Code	Error Description	Possible Cause	Suggested Resolution
12-0108	Channel Configuration for Assay in track Track# does not match related assays in other tracks	Channel configuration or pathogen / target does not match between patient assay, and / or calibrator and control assays	Correct channel configuration and / or pathogen / target
18-0306	Fail to write backup file	Corrupt, or full file receipt location	Try different location or Drive
18-0402	Unable to save. Please specify < > and try again.	Assay editor requirements are not met	Correct requested error and retry save
18-0404	Combinations of PCR Only and Extract + PCR Control and Calibrator Sets are not allowed in the same assay program	Assay editor requirements are not met	Correct requested error and retry save
18-0412	Channel Configuration: Insufficient channels defined for the assay.  Expecting " "	Assay editor requirements are not met	Correct requested error and retry save
18-0417	Unable to save - The Control Set is already used in other assay.	The control set is used in another assay that has already been run	Create a new control set, or delete previous run data for control set
18-0430	Cannot remove the assay : It is required by one or more runs	Assay is required by another assay in the patient, calibrator, or control relationship	To remove assays you must delete calibrator and control set data, then the associated assays
18-4019	Unable to edit - The Assay is already used in template "Template Name"	Assay is part of a template	Delete template before modifying it
18-4020	Unable to edit - The Assay is already Performed	Assay has already been performed	Copy assay before modifying it

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
		Instrument not level	Schedule service visit to investigate root cause
		Extraction failure yielded poor quality eluate	Schedule service visit to investigate root cause
20042	Failed to aspirate eluate.[Track#]	Consumable tip failure	Schedule service visit to investigate root cause
		Single nozzle pipette error  Schedule service visit to investigate root cause	
20053	Unnecessary PP75 tip found.[Track#] Remove from PP75 tip holder. (Caution! Heat Block is hot. Do not touch.)	Tip cassette in a track not selected to run	Remove tip cassette from identified track
20055	No eluate found.[Track#] Set	Consumable tip failure	Schedule service visit to investigate root cause
	eluate(s). (Caution! Heat Block is hot. Do not touch.)	Single nozzle pipette error  Schedule service visit to investigate root cause	
20070	Piercing tip (PP75) dropped unexpectedly.[Track#] Remove the loose piercing tip from the stage.	Piercing tip not seated properly on 12 nozzle pipette	Remove loose piercing tip and continue run
	(Caution! Heat Block is hot. Do not touch.)	Schedule service visit to investigate root cause	
00-0020		Door not shut properly	Close door properly and press lock retry button
	Door lock failed	Door lock not properly aligned	Schedule service visit to investigate root cause

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
00-0021	Door unlock failed	Door is pressed against latch mechanism	Push in slightly on door to release latches
00-0200	To do this, you will need to discard data in run setup screen	Information entered into run setup screen, then attempting to edit assay or access controls or calibrators	Proceeding will cause data in run setup screen to be lost
06-0303	Your account has been locked. Please contact your system administrator.	Too many attempted logins	Login as administrator and reset account
06-0306	User Name not recognized	Mistyped user name	Correct user name and ensure correct case
06-0307	Password not recognized	Wrong password entered	Retry password entry
06-0309	Password must be at least 8 characters	Password is not 8 characters or longer	Retry password entry
06-0311	Invalid Login Attempt : "user name"	Mistyped user name	Correct user name and ensure correct case
06-0312	Invalid Password Entered : "user name"	Incorrect password entered	Enter correct password for user name
06-0402	Current password cannot be used as a new password	Attempted to use current password as new password	Choose a different password and retry
06-0404	Unable to change password - current password not recognized : "user name"	correct current password not entered	Enter correct password for user name
08-0119	Lot number must be at least one character long	Lot number was not entered correctly	Enter a properly formatted lot number

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
08-0135	Control fluid will expire soon YYYY/MM/DD	Expiration value for control is approaching	Run control(s) soon
10-0103	"Control set" Cannot remove Control Set: It is required by one or more assays in the database	Message to warn control set is associated with assays in the database	Control set data can be deleted, but the control set cannot be deleted until the assay is deleted
11-0002	No valid control data is available for Assay[Assay Name]	Control(s) has not yet been completed	Run control(s) before running samples or concurrently with samples
11-0004	No valid calibration curve and control data is available for Assay[Assay Name].	Calibrators and Control(s) have not yet been completed	Run calibrators and control(s) before running samples or concurrently with samples
11-0701	No Calibration curves exist for this assay	Calibration curve has not yet been completed	Run calibrators before running samples or concurrently with samples
11-0703	No Valid Controls exist for this assay - Admin approval will be needed to start the run	Control(s) has not yet been completed	Administrator login needed to start run
11-0705	Calibration and Controls have expired for this assay - Admin approval will be needed to start the run	Calibrators and Control(s) have expired	Administrator login needed to start run
11-0707	No Approved Calibration exists for this assay - Admin approval will be needed to start the run	Calibration curve has not yet been completed	Administrator login needed to start run
11-0710	No Calibration curves exist for this assay	Calibration curve has not yet been completed	Run calibrators before running samples or concurrently with samples
11-0712	No Approved Calibration exists for this assay - Admin approval will be needed to start the run	Calibration curve has not yet been completed	Administrator login needed to start run
11-0713	Controls have expired for this assay - Admin approval will be needed to start the run "Assay Name"	Control(s) have expired	Administrator login needed to start run

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
11-0714	No Valid Controls exist for this assay - Admin approval will be needed to start the run	Control(s) has not yet been completed	Administrator login needed to start run
11-0800	Not allowed to setup a run with multiple instances of calibrators or controls	Multiple calibrators or controls programmed in run setup	Correct run setup error and retry
		Missing consumable	Ensure correct consumable placement
12-0001	Barcode read error occurred Please re-scan the barcode	Misplaced consumable	Ensure correct consumable placement
		Scanning position error	Schedule service visit to investigate root cause
12-0102	Please enter sample IDs for all Patient Assays.[Track#]	Sample ID not entered	Enter sample ID for indicated track
12-0108	Channel Configuration for Assay in track Track# does not match related assays in other tracks	Channel configuration or pathogen / target does not match between patient assay, and / or calibrator and control assays	Correct channel configuration and / or pathogen / target
12-2301	Can't find a valid CALIBRATOR/CONTROL for: Assay:"assay name" Monoreagent Lot Number:######	Control(s) /calibrators have not yet been completed	Run controls / calibrators before running samples or concurrently with samples
12-2302	Can't find a valid CONTROL for: Assay:"assay name" Monoreagent Lot Number:######	Control(s) has not yet been completed	Run control before running samples or concurrently with samples
12-2303	Can't find a valid CALIBRATOR for: Assay: "assay name" Monoreagent Lot Number:######	Calibrators have not yet been completed	Run calibrators before running samples or concurrently with samples
12-3001	It is not possible to run a PCR only control with an E+P calibration curve	Run setup was attempted that violates rules	Correct run setup error and retry

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
12-3003	It is not possible to run a E+P control with a PCR only calibration curve	Run setup was attempted that violates rules	Correct run setup error and retry
14-0001	Invalid results cannot be approved Track=#	Results do not meet criteria prescribed during assay development	Review track report for affected track for criteria that is not acceptable
14-0002	Please approve Calibrator/Control results in the Calibration/Control screen - Track=#	Calibrator or Control result not yet approved	Approve Calibrator or Control
16-0301	Instrument <serial number=""> 1. million (1.000.000) of Optical Fiber Cable approaching</serial>	Optic fiber cycle count has reached 1. million (1.000.000)	Schedule annual service visit to replace fibers
16-0302	Instrument <serial number=""> MM/DD/YYYY lifetime expired on HEPA Filter</serial>	HEPA filter expiration value reached	Schedule annual service visit, or if erroneous reset HEPA Reminder
18-0205	Password and confirmation should be the same	Both passwords do not match	Ensure both passwords match and retry
18-0206	User name must be at least 8 characters	User name is not 8 characters or longer	Add additional characters to user name
18-0306	Fail to write backup file	Corrupt, or full file receipt location	Try different location or Drive
18-0402	Unable to save. Please specify < > and try again.	Assay editor requirements are not met	Correct requested error and retry save
18-0404	Combinations of PCR Only and Extract + PCR Control and Calibrator Sets are not allowed in the same assay program	Assay editor requirements are not met	Correct requested error and retry save
18-0412	Channel Configuration: Insufficient channels defined for the assay.  Expecting " "	Assay editor requirements are not met	Correct requested error and retry save

Error or Warning Code	Error Description	Possible Cause	Suggested Resolution
18-0417	Unable to save - The Control Set is already used in other assay.	The control set is used in another assay that has already been run	Create a new control set, or delete previous run data for control set
18-0430	Cannot remove the assay : It is required by one or more runs	Assay is required by another assay in the patient, calibrator, or control relationship	To remove assays you must delete calibrator and control set data, then the associated assays
18-4019	Unable to edit - The Assay is already used in template "Template Name"	Assay is part of a template	Delete template before modifying it
18-4020	Unable to edit - The Assay is already Performed	Assay has already been performed	Copy assay before modifying it