

23.0331

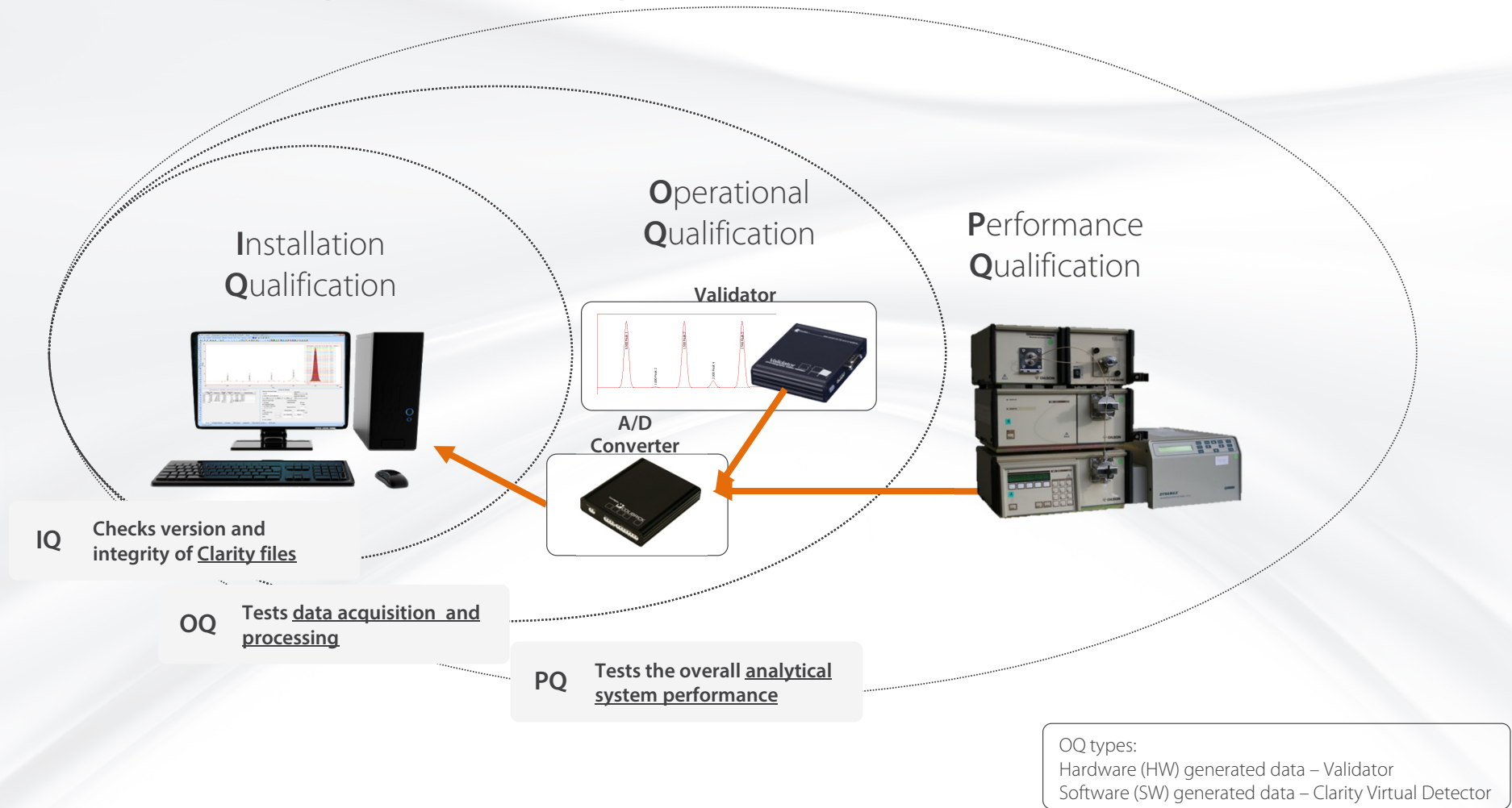


Clarity™

ADVANCED CHROMATOGRAPHY SOFTWARE

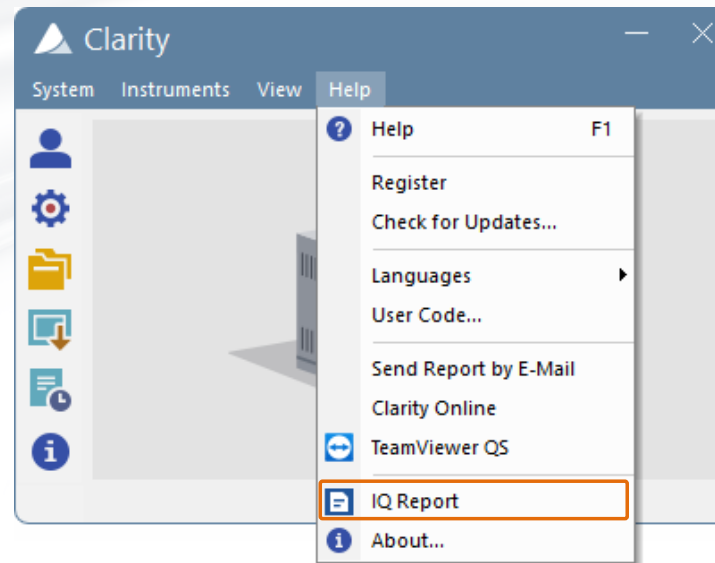
VALIDATION

VALIDATION LEVELS



INSTALLATION QUALIFICATION (IQ)

- Checks version and integrity of Clarity files
- Run from main Clarity window – Help menu



IQ REPORT

IQ
File Help

Installation Qualification Report

Date	23.10.2023, 13:18
Serial number of application	
User Code	
Version of application	Clarity version 9.0.0.82
Build date of application	12.07.2023, 18:42
Instruments	3
Extensions	SST; GPC; PDA; EA; CE; MS; NGA; DHA; GCxGC; MS-TOF
Controls	GC; LC; AS
Certification file	C:\Clarity\Bin\iq.chk
Checksum of cert. file	E69A2CD43B0B8B77
Date of cert. file	12.07.2023, 23:00
User	samuel
System	Microsoft Windows 11 Professional version 10.0 (Build 22621)
Acquisition and hardware devices	Key Rockey S5300 DemoSN DEMO

Core Files, Embedded Components: Failed

Files

[Show files list »](#)

3rd Party Packages

Agilent ICF:

⚠ Agilent ICF is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

Checked by: Signature:

IQ
File Help

Installation Qualification Report

Date	23.10.2023, 13:18
Serial number of application	
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Date of cert. file	12.07.2023, 23:00
User	samuel
System	Microsoft Windows 11 Professional version 10.0 (Build 22621)
Acquisition and hardware devices	Key Rockey 4ND S5300 DemoSN DEMO

Core Files, Embedded Components: Failed

Files

[Hide files list «](#)

File	Path	Version	Size	File date	Status
advantecchf122scfc.rb	c:\clarity\bin\utis\uni_drivers\advantec	-	35747	23.10.2023, 13:17	Failed: bad checksum
AdvionCMS.dll	C:\Clarity\Bin	6.4.14.1	487936	10.03.2021, 17:42	Passed
AdvionCommon.dll	C:\Clarity\Bin	6.4.14.1	30208	12.07.2023, 22:46	Passed
AdvionData.dll	C:\Clarity\Bin	6.4.14.1	315392	12.07.2023, 22:46	Passed
AdvionObjects.dll	C:\Clarity\Bin	6.4.14.1	935424	12.07.2023, 22:46	Passed
agc1290.dll	c:\clarity\bin\hengpinggcms	1.0.7.1	516096	12.07.2023, 22:46	Passed
apix_sdk.dll	c:\clarity\bin\apixchrompix2	2.8.0.1538	3526656	12.07.2023, 22:46	Passed
asi500pump.rb	c:\clarity\bin\utis\uni_drivers\asi	-	46586	12.07.2023, 18:34	Passed

Core Files, Embedded Components: Passed (with warnings)

cswnivm.exe	c:\clarity\installations\9.0.0.82\bin	9.0.0.82	725504	12.07.2023, 18:52	Warning: bad checksum
cswnivm.exe	c:\clarity\installations\9.1.0.14\bin	9.1.0.14	725504	10.08.2023, 03:25	Passed

- General information
- Overall IQ status
 - Passed
 - Passed with warnings
 - Failed
- Status of each file

IQ REPORT

3RD PARTY PACKAGE

Files

[Show files list »](#)

3rd Party Packages

Agilent ICF:

⚠ Agilent ICF is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

Knauer ClarityChrom:

⚠ Knauer ClarityChrom is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

PerkinElmer NexION control module:

⚠ PerkinElmer NexION control module is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

Checked by:

Signature:

- Run separately
- Must be enclosed with Clarity IQ

Knauer Device Drivers for ClarityChrom

Installation Qualification Report

Date	27.10.2023, 13:49
Version of Knauer drivers	8.7.0.6076
User name	DATAAPEX\samuel
Operating system	Microsoft Windows 11 Pro 64-bit Version 10.0.22621 (Build 22621)

Installation Qualification Test: Passed

Files

File	Path	Version	Size	File date	Status
CfgCntlSrv.exe	C:\Program Files (x86)\Knauer\ClarityChrom	8.7.0.6076	56832	08.06.2022, 11:56	Passed
IdentifySrv.exe	C:\Program Files (x86)\Knauer\ClarityChrom	8.7.0.6076	89600	08.06.2022, 11:53	Passed
KCLRS232trExe.exe	C:\Program Files (x86)\Knauer\ClarityChrom	8.7.0.6076	51712	08.06.2022, 11:53	Passed
KnauerIQ.exe	C:\Program Files (x86)\Knauer\ClarityChrom	8.5.0.6055	20480	19.05.2021, 5:53	Passed
LogSetup.exe	C:\Program Files (x86)\Knauer\ClarityChrom	8.7.0.6076	34816	08.06.2022, 11:59	Passed
ASPEN.dll	C:\Program Files (x86)\Knauer\ClarityChrom	1.2.4.0	185344	22.05.2015, 10:25	Passed
CfgCntl.dll	C:\Program Files (x86)\Knauer\ClarityChrom	8.7.0.6076	38400	08.06.2022, 11:53	Passed

Software Verification Report

Date:	Friday, October 27, 2023	Time:	1:55:04 PM [UTC +02:00:00]	Host Name:	PC-067
Windows User Name :	samuel	Base Revision Number:	3.2.64	Product Name :	Agilent ICF
Install Type:	N/A	Additional Packages:	Details		

Base Reference File Name : IQTRef\ICF.xml

Summary :

Overall Evaluation of Installation Check : PASS

File Report Summary

No missing files or invalid files found
No system file difference found

GAC File Report Summary

No missing or invalid GAC files found

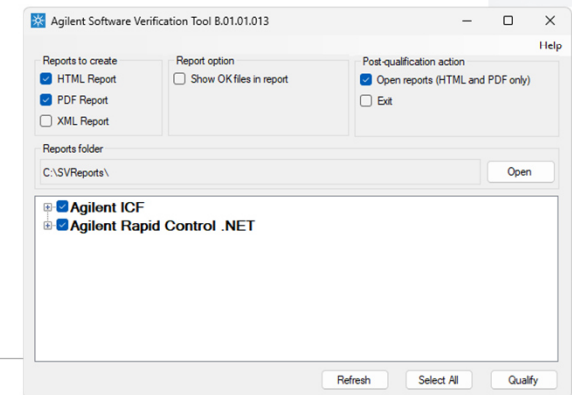
Files Registration Report Summary

Not registered files: NONE
No missing registered files found

Registry Report Summary

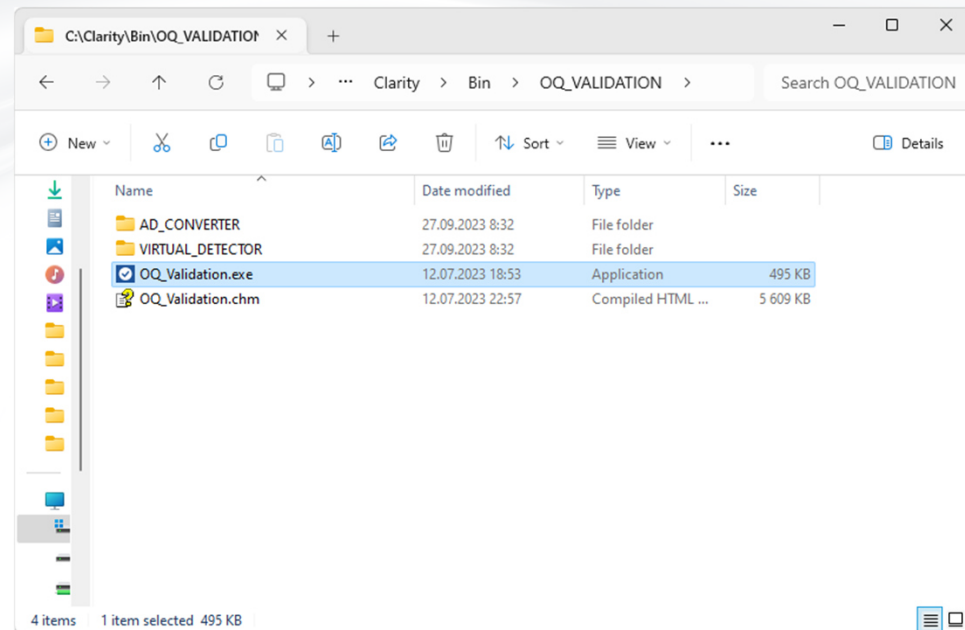
No invalid registry entries found

Details



OPERATIONAL QUALIFICATION (OQ)

- > Test data acquisition and processing
- > Tool supporting 21 CFR Part 11 Regulations
- > Requires **System Suitability Test** (SST) extension
- > **Validation kit** required only for stations with A/D converters



OQ

VALIDATION KIT

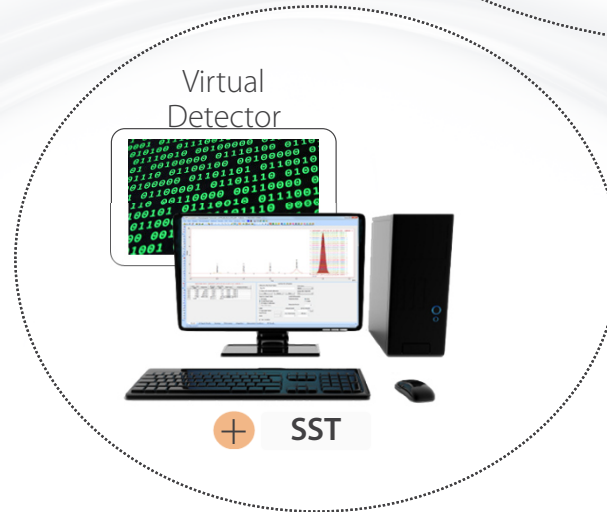
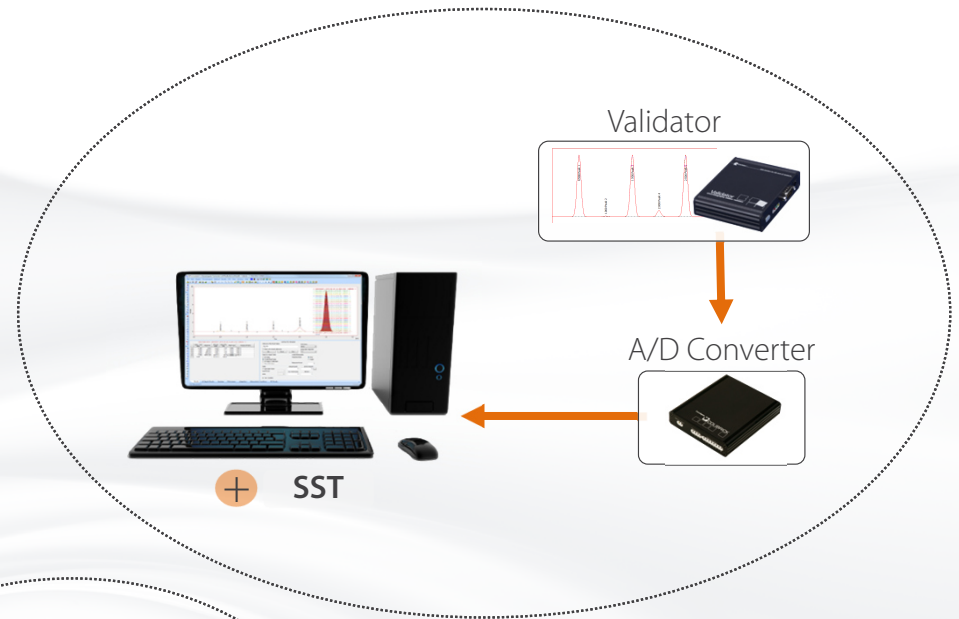
- Validator
- AC/DC power adapter
- Cable for A/D converter
- Terminal board
- Validator certificate



OQ

GENERATING CHROMATOGRAMS

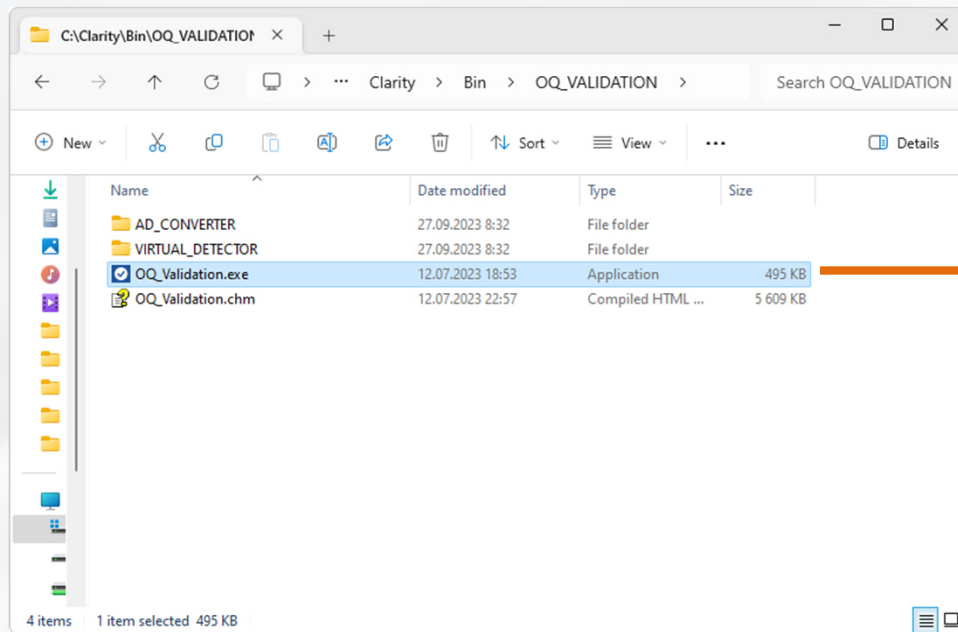
- Validator
 - Station with A/D converter
- Virtual detector
 - Station with only digital acquisition



OQ

WIZARD 1/5

- > Run from ... \Clarity\Bin\OQ_VALIDATION\
- > Avoid printers requiring user response



OQ

WIZARD 2/5

- Select validation type
 - Do you use A/D converter?

OQ Validation - Validation Type

Select validation type

Validation with an A/D converter (HW & SW Validation)

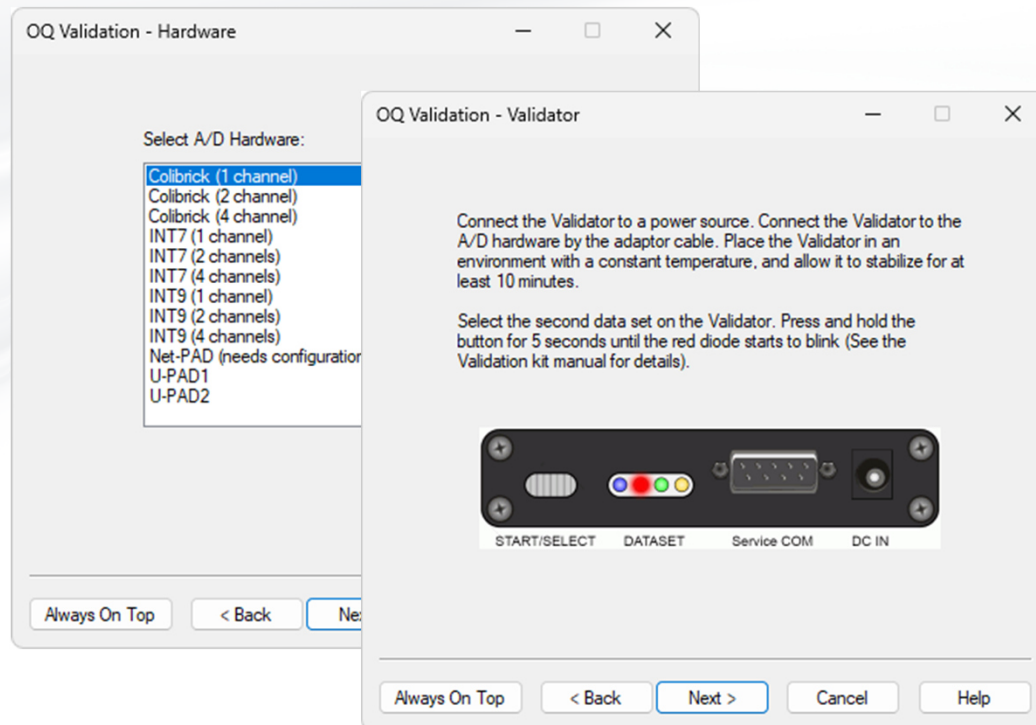
Validation with a Virtual detector (SW Validation only)

Not On Top < Back Next > Cancel Help



WIZARD 3/5

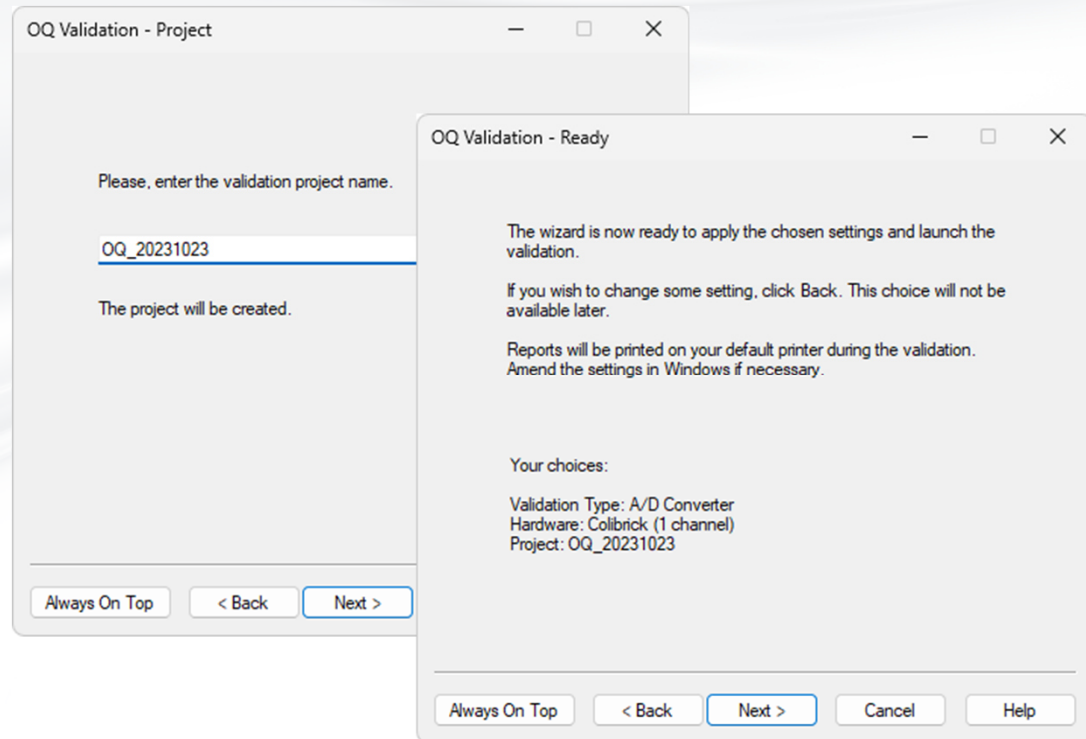
- Exclusive to A/D converter validation
 - Select your HW
 - Let the Validator stabilize
 - Change Validator data set



OQ

WIZARD 4/5

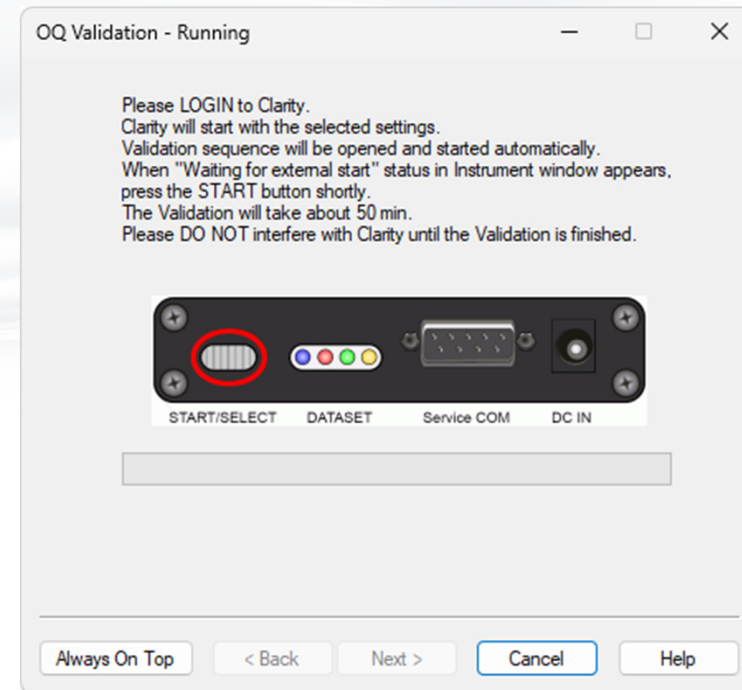
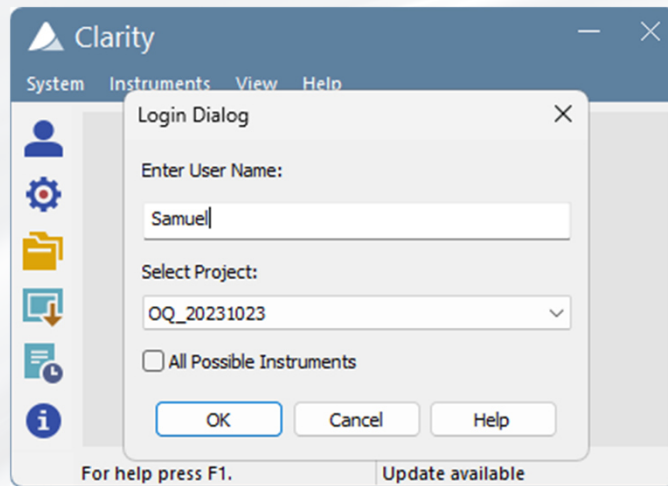
- > Set project name
 - All OQ data will be stored into it
- > Check the summary



OQ

WIZARD 5/5

- > Login to Clarity
- > Press the button on Validator
 - Virtual detector validation starts automatically



OQ

SEQUENCE

- > 3 sets of analyses within 1 sequence
 - Calibration curve linearity
 - Repeatability and precision
 - Acquisition range
- > Each set associated with different method and report style

Status	Run	SV	EV	I/V	Sample ID	Sample	Sample Amount	ISTD1 Amount	Sample Dilut.	Inj. Vol. [μL]	File Name	Sample Type	Lvl	Method Name	Report Style	Open	Open Calib.	Print	Print to PDF	Run Program	Program To Run	Parameters	
1	✓	1	1	1	STD1		0,000	0,000	1,000	0,000	%e_%q...	Stan	1	OQ_CAL		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
2	✓	2	2	1	STD2		0,000	0,000	1,000	0,000	%e_%q...	Stan	2	OQ_CAL		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
3	✓	3	3	1	STD3		0,000	0,000	1,000	0,000	%e_%q...	Stan	3	OQ_CAL		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
4	✓	4	4	1	STD4		0,000	0,000	1,000	0,000	%e_%q...	Stan	4	OQ_CAL		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
5	✓	5	5	1	STD5		0,000	0,000	1,000	0,000	%e_%q...	Stan	5	OQ_CAL	OQ_Linear...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
6	✓	6	6	1	ESTD		0,000	0,000	1,000	0,000	%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	%Self%	""ProjectDir%\OQ_	
7	✓	7	7	1	ESTD		0,000	0,000	1,000	0,000	%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
8	✓	8	8	1	ESTD		0,000	0,000	1		%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
9	✓	9	9	1	ESTD		0,000	0,000	1		%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
10	✓	10	10	1	ESTD		0,000	0,000	1,000	0,000	%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
11	✓	11	11	1	ESTD		0,000	0,000	1,000	0,000	%e_%q...	Unkn		OQ_ESTD		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
12	✓	12	12	1	ISTD1		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	%Self%	""ProjectDir%\OQ_i	
13	✓	13	13	1	ISTD1		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
14	✓	14	14	1	ISTD2		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
15	✓	15	15	1	ISTD2		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
16	✓	16	16	1	ISTD3		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
17	✓	17	17	1	ISTD3		0,000	100,000	1,000	0,000	%e_%q...	Unkn		OQ_ISTD3	OQ_ISTD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	%Self%	delayed_exit=60
18																<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

OQ

RESULTS 1/3 – DATA

- Project folder named according to OQ wizard
- 2 PDF in Data, 1 PDF in Calib

Login Dialog

Enter User Name:

Samuel

Select Project:

OQ_20231023

All Possible Instruments

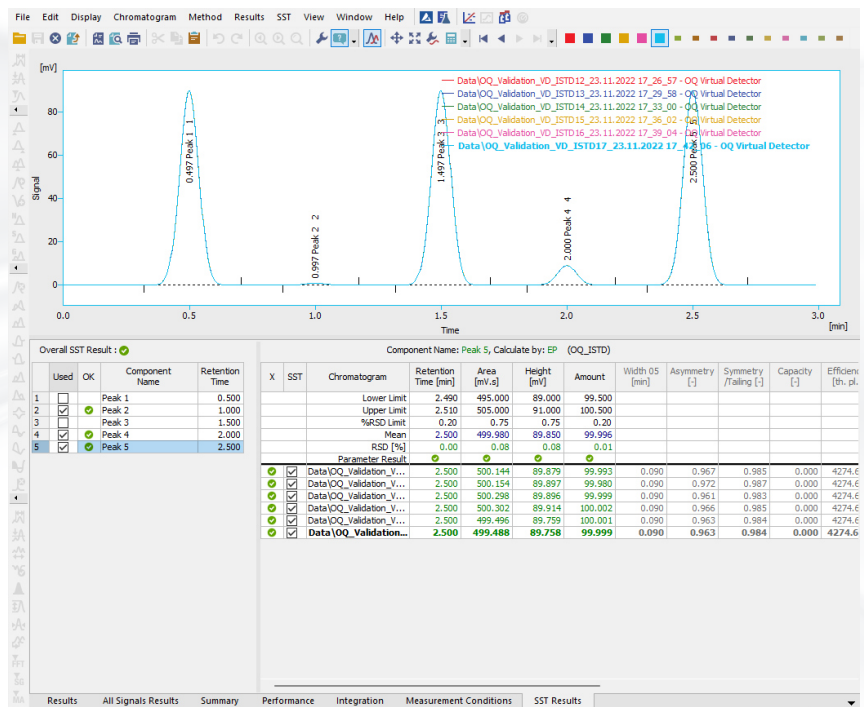
OK Cancel Help

Name	Date modified	Type	Size
Calib	25.10.2023 14:15	File folder	
Data	25.10.2023 14:15	File folder	
OQ_CAL1.met	10.10.2023 15:13	MET Chromatogra...	679 KB
OQ_CAL2.met	10.10.2023 15:13	MET Chromatogra...	679 KB
OQ_CAL3.met	10.10.2023 15:13	MET Chromatogra...	679 KB
OQ_CAL4.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_CAL5.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD.sst	10.10.2023 15:13	SST Chromatogra...	12 KB
OQ_ESTD1.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD2.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD3.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD4.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD5.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ESTD6.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ISTD.sst	10.10.2023 15:13	SST Chromatogra...	12 KB
OQ_ISTD1.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ISTD2.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ISTD3.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ISTD4.met	10.10.2023 15:13	MET Chromatogra...	693 KB
OQ_ISTD5.met	10.10.2023 15:13	MET Chromatogra...	576 KB
OQ_ISTD6.met	10.10.2023 15:13	MET Chromatogra...	809 KB
OQ_SEQ.seq	25.10.2023 14:18	SEQ Chromatogra...	53 KB

OQ

RESULTS 2/3 - EVALUATION

- 1st set must be checked manually
- 2nd and 3rd are checked by SST



Overall SST Result: ✔

Component Name: Peak 5, Calculate by: EP (OQ_ISTD)

Used	OK	Component Name	Retention Time	X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount	Width 05 [min]	Asymmetry [-]	Symmetry /Tailing [-]	Capacity [-]	Efficiency [th. pl.]
1	<input type="checkbox"/>	Peak 1	0.500				Lower Limit	2.490	495.000	89.000	99.500				
2	<input type="checkbox"/>	Peak 2	1.000				Upper Limit	2.510	505.000	91.000	100.500				
3	<input type="checkbox"/>	Peak 3	1.500				%RSD Limit	0.20	0.75	0.75	0.20				
4	<input checked="" type="checkbox"/>	Peak 4	2.000				Mean	2.500	499.980	89.996	99.996				
5	<input checked="" type="checkbox"/>	Peak 5	2.500				RSD [%]	0.00	0.08	0.08	0.01				
Parameter Result															
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation_V...	2.500	500.144	89.879	99.993					0.090	0.967	0.985	0.000	4274.6
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation_V...	2.500	500.154	89.897	99.980					0.090	0.972	0.987	0.000	4274.6
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation_V...	2.500	500.298	89.896	99.999					0.090	0.961	0.983	0.000	4274.6
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation_V...	2.500	500.302	89.914	100.002					0.090	0.966	0.985	0.000	4274.6
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation_V...	2.500	499.496	89.759	100.001					0.090	0.963	0.984	0.000	4274.6
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data\OQ_Validation...	2.500	499.488	89.758	99.999					0.090	0.963	0.984	0.000	4274.6



RESULTS 3/3 – OQ REPORT

- 3 PDF files from OQ project folder
- Protocol

DataApex
ADVANCED CHROMATOGRAPHY SOFTWARE

Headline (2017.1), 10000 Rows, Top Check Report

Certificate of chromatography station validation

Certificate No: _____
User: _____

Software: _____
Version: _____
SN: _____
A/S Batch: _____
Computer: _____
Operating System: _____
Validation: _____

The chromatography datastation specified above was properly installed and its functionality verified by procedure developed by the DataApex, Ltd. This certificate confirms, that the station is functional and performs according to manufacturer's specifications. Part of this certificate are the Installation Qualification Report and properly checked and signed records of the Calibration/Linearity Test, SST Calculation Test & STD Calculation Test.

The Validation was performed by:

Validation performed by: _____ Signature: _____ Date: _____
Authorization number: _____
Company name: _____

User: _____ Signature: _____ Date: _____

www.dataapex.com (202406) contact Code/Version: 0004/0001 (202404) Page 1 of 17

Clarity - Operational Qualification
Calibration linearity test
© DataApex 2023, www.dataapex.com

Peak 1 - Signal 1 - 0.467 min

Peak Type: Other
Search Window: Absc
Left Window: 0.200 min
Right Window: 0.200 min
Peak Selection: Nearest
Response Base: Area
iNSTD: None
Use STD: None
Curve Fit Type: Linear
Origin: Ignore Origin
Weighting Method: 1/Response
Linearization X: None
Linearization Y: None
Correlation Factor: 1.0000
Calculate By: 1
Conversion Factor: 0.00143 (µV/g)
Equation: $Y = 500.05897X + 0.0394$

Clarity - Operational Qualification
ESTD calculation test
© DataApex 2023, www.dataapex.com

SST Component Table

Component	Retention Time
1	0.500
2	1.000
3	1.500
4	2.000

SST Result for Component "Peak 1": Calculate By "SP"

Chromatogram

SST Parameters Table

Lower Limit	Upper Limit	Mean	SD
0.997	1.003	0.999	0.002

Parameter Result:

Retention Time (min)	Area (µV/g)	Height (µV)	Amount
0.997	4.500	0.999	0.999
1.003	5.500	0.997	1.000
4.973	4.994	0.997	0.994
4.981	4.994	0.997	0.994
4.989	4.994	0.997	0.994
4.997	4.994	0.997	0.994

SST Result for Component "Peak 2": Calculate By "SP"

Chromatogram

SST Parameters Table

Lower Limit	Upper Limit	Mean	SD
1.997	2.003	1.999	0.002

Parameter Result:

Retention Time (min)	Area (µV/g)	Height (µV)	Amount
1.997	8.500	1.999	1.999
2.003	9.500	1.997	2.000
8.973	8.994	1.997	1.994
8.981	8.994	1.997	1.994
8.989	8.994	1.997	1.994
8.997	8.994	1.997	1.994

SST Result for Component "Peak 3": Calculate By "SP"

Chromatogram

SST Parameters Table

Lower Limit	Upper Limit	Mean	SD
2.997	3.003	2.999	0.002

Parameter Result:

Retention Time (min)	Area (µV/g)	Height (µV)	Amount
2.997	12.500	2.999	2.999
3.003	13.500	2.997	3.000
10.973	10.994	2.997	2.994
10.981	10.994	2.997	2.994
10.989	10.994	2.997	2.994
10.997	10.994	2.997	2.994

SST Result for Component "Peak 4": Calculate By "SP"

Chromatogram

SST Parameters Table

Lower Limit	Upper Limit	Mean	SD
3.997	4.003	3.999	0.002

Parameter Result:

Retention Time (min)	Area (µV/g)	Height (µV)	Amount
3.997	16.500	3.999	3.999
4.003	17.500	3.997	4.000
14.973	14.994	3.997	3.994
14.981	14.994	3.997	3.994
14.989	14.994	3.997	3.994
14.997	14.994	3.997	3.994

Expected values for Subst Equation: $Y = \text{Slope} \times X + \text{Of}$

Slope: 500 ± 2
Offset: 0.0 ± 0.5
Correlation: > 0.99999

TEST Result:

TEST Re

TEST Result: Passed [] Signature: _____

OQ

WHO CAN PERFORM?

- > Validation training
- > DataApex issued certificate
- > Valid for 5 years

CERTIFICATE

OF ACHIEVEMENT

THIS CERTIFICATE IS PROUDLY PRESENTED TO

For successful completion of the Clarity Validation Kit Training.
The trained person is entitled to perform Validation service on behalf of DataApex Company.
The Certificate is valid for five years since the issuance date.

Prague 19.5.2023

Date



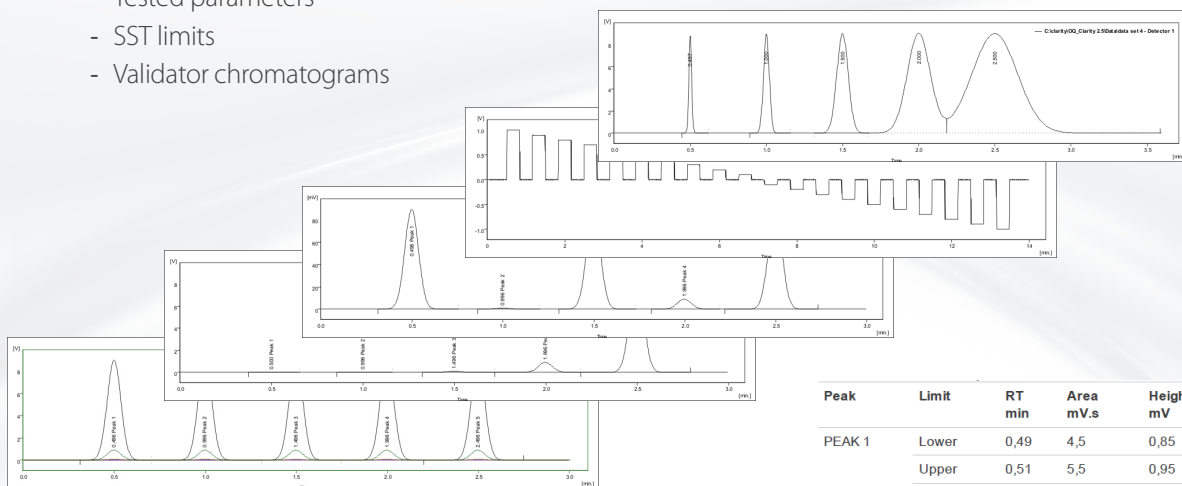
Ivan Vint

Ivan Vint
Clarity Product Manager

OQ

ADDITIONAL INFO

- Validation kit manual
 - Tested parameters
 - SST limits
 - Validator chromatograms



Peak	Limit	RT min	Area mV.s	Height mV	Amount
PEAK 1	Lower	0,49	4,5	0,85	0,009
	Upper	0,51	5,5	0,95	0,011
	RSD%	1,5	2	2	2

PERFORMANCE QUALIFICATION (PQ)

- Compliance with SOPs and workflow of given workplace
- SST could be used
- Must be prepared by the workplace personnel based on:
 - Used devices
 - SOPs
 - Regulations
- IQ and OQ must be successful before doing PQ
- No certificate for PQ is issued by DataApex

23.0331



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THANK YOU FOR YOUR ATTENTION