

## Clarity Validation Kit for Operational Qualification



DataApex  
**Clarity**<sup>™</sup>  
Validation Kit

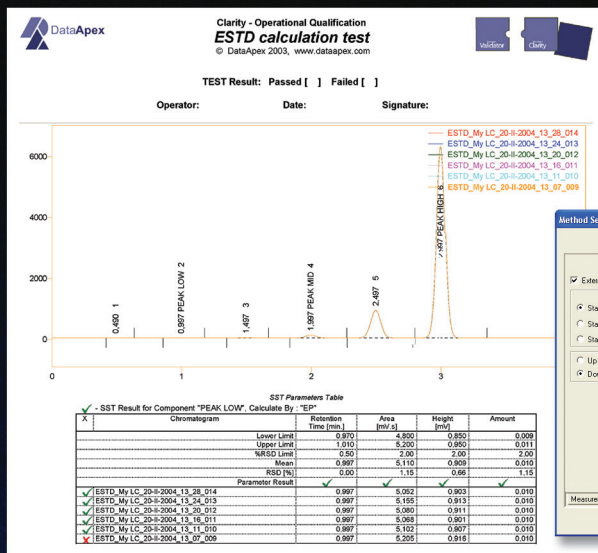
### Clarity Validation Kit:

- Clarity Validator (precise analog signal generator device)
- Clarity Validation Kit Manual
- CD with all files necessary for performing the Operational Qualification
- Cables



# Operational qualification tests:

- Retention time precision and accuracy
- Voltage (peak height) measurement precision and accuracy
- Area determination precision and accuracy
- Calibration and calculations – ESTD and ISTD methods
- Consistency of acquisition ranges



Seq	Run	SV	EV	IV	Sample ID	Sample	Sample Amount	ISTD Amount	Sample Dil.	Hi Vol Lvl	File Name	Std	Lvl	Method Name	Report Style
1	1	1	1	1	0.00 %	SET %	0.000	0.000	1.000	0.000	SET %	Yes	1	prog...	
2	2	2	2	2	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	6	Linea6	
3	3	3	3	3	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	5	Linea5	
4	4	4	4	4	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	4	Linea4	
5	5	5	5	5	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	3	Linea3	
6	6	6	6	6	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	2	Linea2	
7	7	7	7	7	1.00 %	LINEARITY %	0.000	0.000	1.000	0.000	LN %	Yes	1	Linea1	OQ_Linearity
8	8	8	8	8	1.00 %	ESTD %	0.000	0.000	1.000	0.000	ESTD %	No	1	ESTD	
9	9	9	9	9	1.00 %	ESTD %	0.000	0.000	1.000	0.000	ESTD %	No	1	ESTD	
10	10	10	10	10	1.00 %	ISTD %	0.000	0.000	1.000	0.000	ISTD %	No	1	ISTD	
11	11	11	11	11	1.00 %	ISTD %	0.000	0.000	1.000	0.000	ISTD %	No	1	ISTD	

Event Type	Threshold Value	Output #	Output Level
1	Time >	0.05	Low
2	Time >	0.08	Low
3	Time >	0.07	High
4	Time >	0.09	Low
5	Time >	0.09	Low
6	Time >	0.10	High
7	Time >	0.11	Low
8	Time >	0.12	Low
9	Time >	0.12	High
10	Time >	0.14	Low
11	Time >	0.15	Low
12	Time >	0.15	High
13	Time >	0.17	Low
14	Time >	0.18	Low
15	Time >	0.19	High
16	Time >	0.20	Low
17	Time >	0.21	Low
18	Time >	0.22	Low

The quality of analytical data is an issue gaining increased attention in many laboratories today. One condition for ensuring the reliability of generated results lies in the validation of all instrumentation and procedures used for the acquisition of said data.

Commonly, three levels of validation (qualification) are relevant for chromatography data stations:

### Installation Qualification:

a procedure confirming that the data station was successfully installed and that the installation contains all the required files of the correct version. Installation qualification is an integral part of the Clarity Chromatography data station installation procedure.

### Operational Qualification:

a procedure confirming that the data station is performing according to the manufacturer's specification.

The Clarity Validation kit serves this purpose.

Using a precise peak generator, chromatographic data is acquired and analyzed with prepared procedures and the acquired results are compared with expected values.

### Performance Qualification:

a procedure confirming that the analytical system is fit for a given type of analysis. Usually, the overall system performance is tested by this procedure with respect to the requirements of the desired application. The Clarity data station offers many tools in the System Suitability Test (SST) module to efficiently evaluate the system performance.

The Clarity Validation Kit is designed to perform the Operational Qualification of the Clarity Chromatography Station (version 2.2 or higher) with INT7 or U-PAD A/D converters. An optional Clarity SST module is necessary for data evaluation.

The kit is primarily intended for trained service personnel, who regularly perform validations of chromatography systems using Clarity data stations. However it can also be used by experienced users for in-house validations. The operator must be familiar with Clarity data station operations.

