

Rev. 23.2.2004

## Clarity Validation kit for Operational Qualification

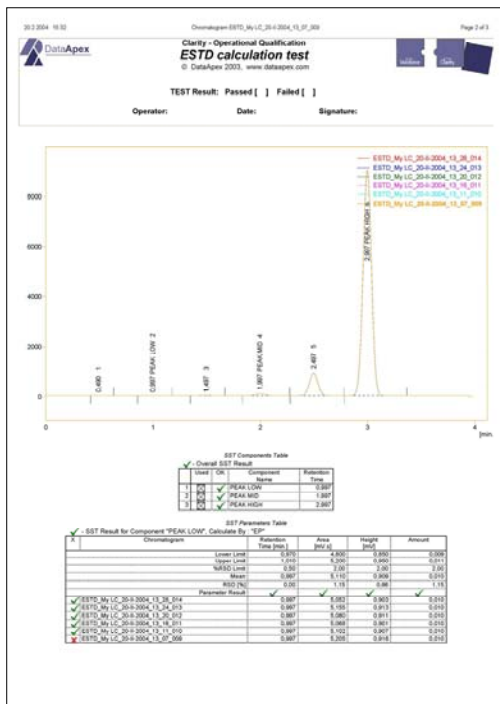
The quality of analytical data is an issue gaining increased attention in many laboratories today. One condition for ensuring the reliability of generated results lies in the validation of all instrumentation and procedures used for the acquisition of said data.

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

**Installation Qualification:** a procedure confirming that the datastation 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 datastation installation procedure.

**Operational Qualification:** a procedure confirming that the datastation 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 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.



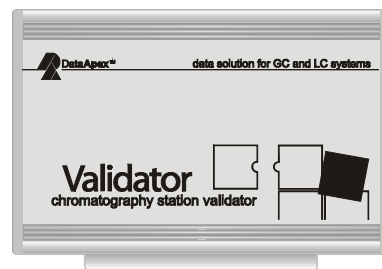
Run	Sample	Sample Amount	ESTD Amount	Sample Size	Inj Vol	File Name	Method Name
1	1	0.000	0.000	1.000	0.000	SET_Neg	Yes
2	2	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
3	3	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
4	4	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
5	5	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
6	6	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
7	7	0.000	0.000	1.000	0.000	LINEARV_Neg...	Yes
8	8	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
9	9	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
10	10	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
11	11	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
12	12	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
13	13	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
14	14	0.000	0.000	1.000	0.000	ESTD_Neg_Neg	No
15	15	0.000	10.000	1.000	0.000	ESTD_Neg_Neg	Yes
16	16	0.000	10.000	1.000	0.000	SET_Neg_Neg	Yes
17	17	0.000	10.000	1.000	0.000	ESTD_Neg_Neg	No
18	18	0.000	10.000	1.000	0.000	ESTD_Neg_Neg	No
19	19	0.000	10.000	1.000	0.000	ESTD_Neg_Neg	No

**During operational qualification, following parameters are tested:**

- **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**

The **Clarity Validation Kit** consists of:

- Clarity Validator (precise analog signal generator device)
- Clarity Validation Kit Manual
- CD with sequence, method, calibration, report and other files necessary for performing the Operational Qualification.
- USB cable (power supply for Validator only)
- Flat extension cable



The **Clarity Validation Kit** is designed for performing **Operational Qualification** of **DataApex Clarity Chromatography Station** version 2.2 or higher, with **INT7** or **U-PAD** A/D converters. 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 be also used by experienced users for in-house validations. The operator must be familiar with the **Clarity** data station operations.

For more information contact [dataapex@dataapex.com](mailto:dataapex@dataapex.com)

**DataApex** Company, established in 1991, is a developer and manufacturer of chromatography software. The DataApex data stations are used for data acquisition, evaluation and instrument control. The products are sold to more than 45 countries around the world and 5 chromatography instrument manufacturers resell privately labeled version of DataApex software.