

A red circular icon with a white arrow pointing clockwise, indicating a refresh or update action.

QbD1200+ Analyzer NDIR Stability Study

Background

Water for pharmaceutical purposes requires ensuring high purity with low levels of organic compounds, as contamination and lack of purity are a risk to patient safety. Total Organic Carbon (TOC) is widely used in Pharmaceutical Quality Control Laboratories to monitor purity and ensure that levels of organic compounds are within acceptable limits.

The QbD1200+ is designed to measure TOC and meet the performance requirements necessary for Pharmacopeia and GMP compliance. As with any measurement tool, it is important to monitor the device's optimum condition and verify it before use. Monitoring can be done by running scheduled tests on designed traceable standards at a pre-defined cadence, with results indicating overall performance.

Key components of the analyzer, such as the **non-dispersive infrared (NDIR) detector** can also be monitored to ensure accurate and reliable results. In addition to the tests using traceable standards, System Health Tests automatically performed before sample analysis verify the performance of the NDIR. The system will generate an error message if the NDIR is not performing to specifications. Users can visualize and plot the data acquired during the health test within a desired time range or throughout its entire life.

Introduction

The QbD1200+ analyzer uses UV light and a reagent to oxidize organic matter, generating CO₂. The amount of CO₂ generated is proportional to the amount of Total Organic Carbon in the sample. The amount of IR light absorbed by CO₂ molecules in a sample is proportional to the number of CO₂ molecules in the sample. The QbD1200+ analyzer uses an NDIR detector that is the most common type of sensor used to measure CO₂. The NDIR detector should be stable over time to guarantee the accuracy and reliability of sample measurements. For this Technical Note, *TOC Standard 500ppb* and signal of the NDIR measured during System Health Tests were monitored to evaluate the stability of the QbD1200+ analyzer, over a 6-month and 8-month period, respectively.

Procedure

Instrument setup: Configure the Instrument as shown on Figure 1. Place Flush in position 1, Blank water in position 2 and 500ppb Solution in position 3 of the autosampler and press **Start**.

Results can be retrieved as .CSV or PDF (**Figure 2**).

QbD1200+

Measurement Settings

Default Settings

Number of Locations (Range: 0-64)

Number of Replicates (Range: 1-5)

Default Label Selection
Automatic Time/Date Stamp

Default View
☒ Tray View ☐ Table View

Fast Mode
☐ Fast Mode

Process Settings

Auto Ranging
☒ Enable Autorange

Conditioning
☒ Enable Conditioning

Process Options
☐ Homogenize Sample
☐ Backflush
☐ Enable Dilution Factor
☐ Enable Sample Detection
☐ Adjust Temperature

Temperature Target (C)

Background Measure Times

Results Display Settings

Measurement Units
☐ Use SI Units
☒ ppm ☒ ppb

Pressure Units
☒ Psi ☐ mbar

TIC Analysis
☐ Display TIC Values

Measurement Rejection
☐ Enable Rejection

☒ First Rep ☐ Outliers

Results Precision

Cancel Save

4/16/2025 07:08 PM Service

Figure 1. QbD1200+ analyzer settings for NDIR Stability Monitoring.

	A	B	C	D	E	F	G	H
1	Output Fil From Date To Date: 8/19/2024							
2	Measurement							
3	Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
4	1	Flush	#####		3:54 PM	1	9	
5	1	Flush	#####		4:00 PM	2	5	
6	1	Flush	#####		4:06 PM	3	5	
7					Avg		6.4	
8					Std Dev		2.2	
9					RSD (%)		34.5	
10	Autorange Enabled							
11								
12	Measurement							
13	Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
14	2	Water Blar	#####		4:19 PM	1	4	
15	2	Water Blar	#####		4:25 PM	2	6	
16	2	Water Blar	#####		4:31 PM	3	6	
17					Avg		5.6	
18					Std Dev		1.1	
19					RSD (%)		19.1	
20	Autorange Enabled							
21								
22	Measurement							
23	Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
24	3	0.5 ppm si	#####		4:45 PM	1	489	
25	3	0.5 ppm si	#####		4:52 PM	2	508	
26	3	0.5 ppm si	#####		5:00 PM	3	503	
27					Avg		500.3	
28					Std Dev		9.8	
29					RSD (%)		2	
30	Autorange Enabled							
31								
32								
33	Background							
34	Info	Value						
35	User Name							
36	Date	#####						
37	Time	3:17 PM						
38	Results	Accepted						
39	Std Dev	2.5						
40	Backgrour	11						
41	Primary Lot	11232023						
42	Expiration	#####						
43	Secondary C	1-08192024						
44	Dilution D	#####						
45	Calibration	01:06 AM						

							Results
Output Filter : From Date: 8/19/2024, To Date: 8/19/2024							
Measurement							
Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
1	Flush	#####	8/19/2024	03:54 PM	1	9	
1	Flush	#####	8/19/2024	04:00 PM	2	5	
1	Flush	#####	8/19/2024	04:06 PM	3	5	
				Avg		6.4	
				Std Dev		2.2	
				RSD (%)		34.5	
Autorange Enabled							
Measurement							
Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
2	Water Blank	#####	8/19/2024	04:19 PM	1	4	
2	Water Blank	#####	8/19/2024	04:25 PM	2	6	
2	Water Blank	#####	8/19/2024	04:31 PM	3	6	
				Avg		5.6	
				Std Dev		1.1	
				RSD (%)		19.1	
Autorange Enabled							
Measurement							
Pos	User Name	Sample ID	Date	Time	Rep	TOC (ppb)	
3	0.5 ppm sol	#####	8/19/2024	04:45 PM	1	489	
3	0.5 ppm sol	#####	8/19/2024	04:52 PM	2	508	
3	0.5 ppm sol	#####	8/19/2024	05:00 PM	3	503	
				Avg		500.3	
				Std Dev		9.8	
				RSD (%)		2.0	
Autorange Enabled							
Background							
User Name							
Date							8/19/2024

Figure 2. Results of monitoring individual set of tests exported as .CSV or PDF format.

Contents	Sample	Date	TOC (ppb Avg)	Std Dev	RSD (%)
1	Flush	8/19/2024	6.4	2.2	
2	Water Blank	8/19/2024	5.6	1.1	
3	500 ppb sol	8/19/2024	500.3	9.8	2
1	Flush	8/29/2024	19.3	1.6	
2	Water Blank	8/29/2024	9.8	1.6	
3	500 ppb sol	8/29/2024	515.2	1.8	0.4
1	Flush	9/19/2024	5.2	2.3	
2	Water Blank	9/19/2024	3	1.6	
3	500 ppb sol	9/19/2024	503.9	3.4	0.7
1	Flush	9/23/2024	6.6	1.2	
2	Water Blank	9/23/2024	6.5	1	
3	500 ppb sol	9/23/2024	516.5	5	1
1	Flush	2/19/2025	6.5	0.4	
2	Water Blank	2/19/2025	5.1	0.9	
3	500 ppb sol	2/19/2025	533	4.5	0.8
1	Flush	2/24/2025	8.2	1.5	
2	Water Blank	2/24/2025	6.2	1.4	
3	500 ppb sol	2/24/2025	535.9	2.7	0.5

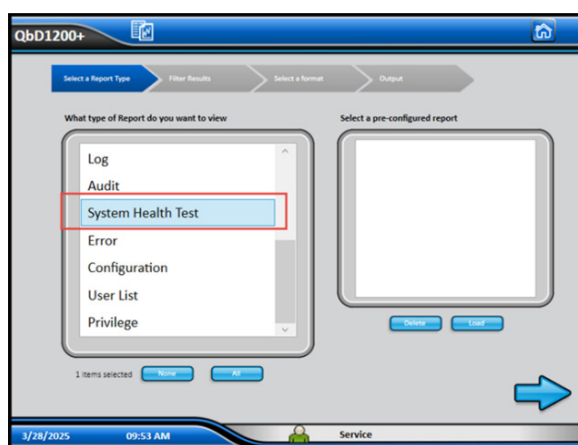
Table 1. NDIR stability tests with TOC Standard 500 ppb from August 2024 to February 2025 using auto sampler, flush sample, water and 500ppb. The values correspond to the average of three runs for each sample. Note that RSD for flush and blanks are not relevant, as the events are naturally random, and thus, not shown in the table.

In addition to the monitoring tests above, System Health Tests measure and report pass/fail status of the NDIR responses and save them before running samples. NDIR data can be retrieved following the steps below and the trend graph with upper and lower limits can be plot as shown in Figure 4, where the blue curve shows stable NDIR over about an eight-month period.

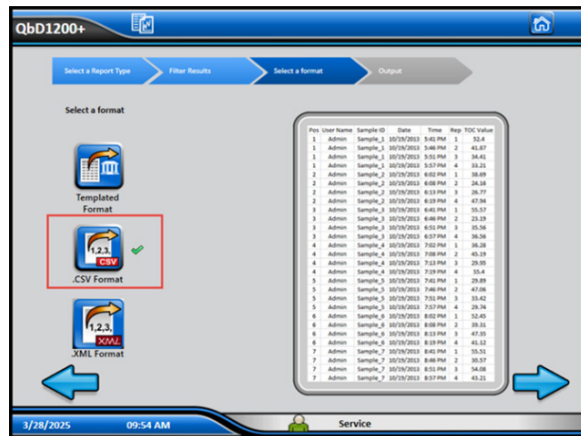
1. Select Reports and Data from Main Screen.



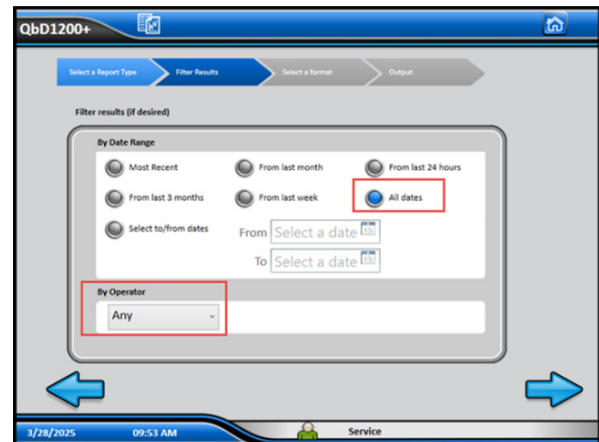
1. Select System Health Test in the list.



3. Select All dates and Any operator.



4. Select .CSV format.



5. Export to USB or to the network.



Test ID	Test Run	Compo	Date	Time	Results	Lower L	Upper L	Passed
653	108	Ndir	7/29/2024	11:19 PM	3331.3	2200	3600	Passed
667	109	Ndir	7/30/2024	12:36 AM	3356.2	2200	3600	Passed
671	110	Ndir	7/30/2024	1:17 AM	3359.7	2200	3600	Passed
692	111	Ndir	7/29/2024	4:00 AM	3366.7	2200	3600	Passed
723	112	Ndir	7/29/2024	4:04 PM	3367.1	2200	3600	Passed
737	113	Ndir	7/30/2024	2:31 PM	3360.7	2200	3600	Passed
741	114	Ndir	7/30/2024	2:57 PM	3363.9	2200	3600	Passed
745	115	Ndir	7/30/2024	3:04 PM	3365.7	2200	3600	Passed
27845	6837	Ndir	4/2/2025	12:40 PM	3435.5	2200	3600	Passed
27849	6838	Ndir	4/2/2025	12:51 PM	3434.9	2200	3600	Passed
27853	6839	Ndir	4/2/2025	12:58 PM	3434.5	2200	3600	Passed
27857	6840	Ndir	4/2/2025	1:05 PM	3434	2200	3600	Passed
27861	6841	Ndir	4/2/2025	1:16 PM	3433.6	2200	3600	Passed
27865	6842	Ndir	4/2/2025	1:24 PM	3435.8	2200	3600	Passed
27869	6843	Ndir	4/2/2025	1:31 PM	3436.4	2200	3600	Passed

Figure 3: NDIR stability data with System Health Tests data from 7/29/2024 through 4/02/2025 (partial list of runs shown).

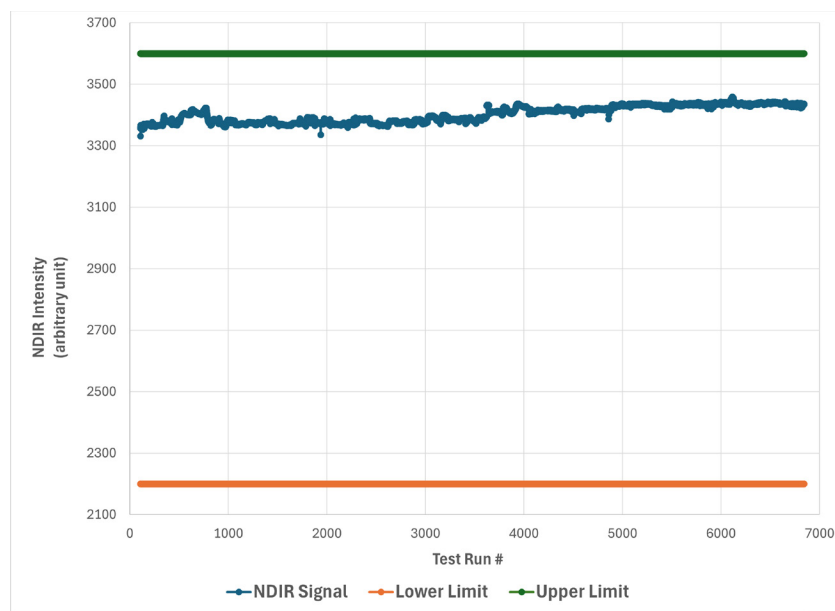


Figure 4: NDIR stability plot for data with System Health Tests data from 7/29/2024 through 4/02/2025. The NDIR Signal blue line indicates the NDIR response remained stable over the 8-month period of this study.

Conclusion

Monitoring measurements on *System Suitability Test 500ppb* and the signal from the NDIR measured during the System Health Check have shown a very good detector stability over a period of 8 months, confirming the ability of the QbD1200+ TOC analyzer to provide stable results over a long period of time without frequent recalibration.

Beckman Coulter Life Sciences would also like to thank Andrew Walsh, and the team from the Center for Pharmaceutical Cleaning Innovation (CPCI™) in New Jersey, for providing all the data used in this technical note.