

QbD1200 Application Note

JP SDBS Validation



JP 16, section 2.59 Test for Total Organic Carbon

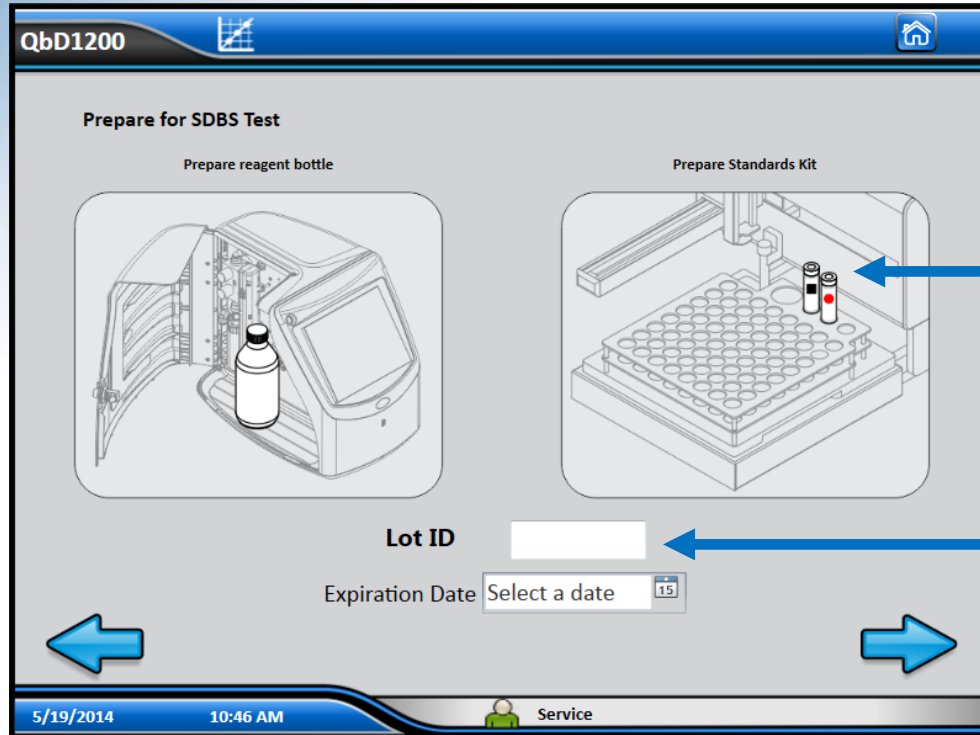
JP 16 specifies that when measuring a 500ppb standard of sodium dodecylbenzenesulfonate (SDBS), a TOC analyzer should recover a value of at least 450ppb (90% recovery). As SDBS is known to be a compound considered hard to oxidize, successful measurement would indicate that the TOC analyzer has been validated to be functioning properly.

The QbD1200 has a built in qualification routine, "SDBS", which makes performing a JP 16 compliant validation convenient. Two standard solutions are used:

- Blank water
- 500 ppb SDBS

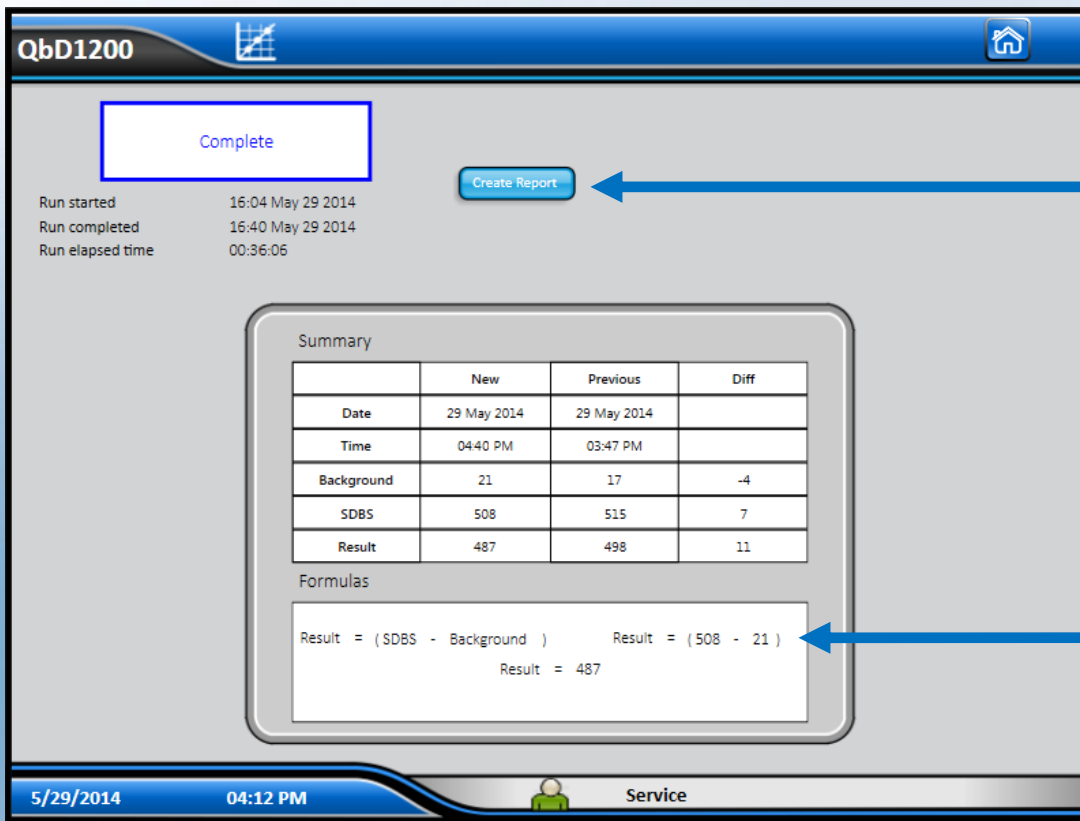
After three replicate measurements are taken of each solution, the average value of the blank water is subtracted from the average value of the SDBS measurements and the result is displayed.

QbD1200 is designed so that SDBS Validation is very convenient and easy to perform.



Instrument display guides operator where to place standards

Enter standards lot number and expiration date



QbD1200

Complete

Run started 16:04 May 29 2014
Run completed 16:40 May 29 2014
Run elapsed time 00:36:06

Create Report

Summary

	New	Previous	Diff
Date	29 May 2014	29 May 2014	
Time	04:40 PM	03:47 PM	
Background	21	17	-4
SDBS	508	515	7
Result	487	498	11

Formulas

Result = (SDBS - Background) Result = (508 - 21)
Result = 487

5/29/2014 04:12 PM Service

Option to send report
Paperless over
Ethernet (secure FTP)

Results Clearly
Shown

Notes:

- JP requires that a TOC Analyzer be validated to recover ≥ 450 ppb Carbon from 500ppb SDBS standard.
 - ✓ QbD1200 is designed to make this process convenient.
 - ✓ Standards use color coded shapes to ensure proper placement in auto sampler rack.
 - ✓ All standards are measured with 3 replicates.
 - ✓ SDBS validation procedure takes approximately 35 minutes.
 - ✓ Paperless reporting allows operator to easily store all important qualification results on central server and maintain 21 CFR 11 compliance.

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