Low TOC – 500 ppb KHP	
Business Partner / End User:	ABC Company
Reference Number:	FAR-002000
Product Line:	Consumables
Part Number:	STD 74509-01 500 Super iOS Specificity Set
Case-RMA:	N/A
Lot Number:	23000-1234
Analysts:	Victor Rink
Author:	Victor Rink
Date of Failure:	4 Oct 2023
Revision:	A
Reported Issue:	Customer reported low TOC on a 500 ppb TOC KHP standard (STD 74050) in a 500 Specificity Set

SECTION 1

Root Cause Analysis:

Customer reported a STD 74050 (500 ppb KHP) standard measuring abnormally low at 261 ppb during a Specificity Set protocol, causing low recovery (50.3%) and the Specificity test to fail (see Table 1 below).

Table 1 – Customer Data

Blank Correction = 18.7 ppb **Adj Std Concentration** = 519 ppb			
	500 ppb Methanol	**500 ppb Nicotinamide**	**500 ppb KHP**
TOC	525 ppb	520 ppb	261 ppb
SD	1.00 ppb	0.00 ppb	10.2 ppb
RSD	0.19%	0.00%	3.91%
% Recovery	101%	100%	50.3%
% Recovery Range: 85% - 115% **Specificity Pass/Fail:** FAIL			

Review of customer field data for Lot 23000-1234 shows no other incidents of low TOC. Retain data of Lot 23000-1234 measured within specifications and passed the Specificity test requirements (see Table 2 below). Given these observations, this case appears to be an isolated incident.

Table 2 – Retain Data

Blank Correction = 10.2 ppb **Adj STD Concentration** = 510 ppb			
	500 ppb Methanol	**500 ppb Nicotinamide**	**500 ppb KHP**
TOC	510 ppb	509 ppb	493 ppb
SD	2.08 ppb	3.51 ppb	1.00 ppb
RSD	0.41%	0.69%	0.20%
% Recovery	100%	99.8%	96.7%
% Recovery Range: 85% - 115% **Specificity Pass/Fail:** PASS			

A team of Consumables personnel reviewed manufacturing records and the customer's instrument data to investigate possible root causes. Quality Control data confirm that STD 74050 passed TOC measurement on the day of manufacture. Production logs reveal that no standards of 250 ppb TOC concentration were manufactured on the same day as Lot 23000-1234, which excludes the possibility of a mislabeled vial or cross-contamination with another solution.

SECTION 1	
	The customer's instrument data for 500 ppb KHP from Lot 23000-1234 shows elevated standard deviation (10.2 ppb), indicating instability in the measurement. Additionally, the average IC of the 500 ppb KHP standard was 8.94 ppb, which is significantly lower compared to the other standards in the Specificity Set, including the water blank (average IC = 102 ppb). Furthermore, the following measurement of Reagent Water on the customer's instrument (Robustness Test on 2 Oct 2023 14:15) shows abnormally low levels of TOC (-0.11 ppb), IC (3.36 ppb), and TC (3.24 ppb); these are unlikely to be real values given equilibration of water with CO_2 in the environment and by comparison to other water standard measurements from the customer's instrument from 1 Oct – 2 Oct 2023. Given this information, the Consumables team concluded that the flow of the sample in the instrument was interrupted during measurement of these two standards, which resulted in the low TOC, IC, and TC measurements.

SECTION 2	
Corrective Action:	It is difficult to determine the exact root cause of the interruption of sample flow in the customer's instrument. It is recommended that the instrument tubing of the sample flow loop be checked for pinched points or blockages. Quality data will continue to be collected and trended to monitor low TOC incident rates. If there is a significant change in rate of failure, a team will be dedicated to performing an investigation and implement further corrective action.

SECTION 2: Conclusions

Likely root cause of the low TOC measurement was identified, and corrective actions suggested. Customer data is reviewed monthly and our team is dedicated to improving the quality of our standards. To provide assistance and troubleshooting in a timely manner, it is recommended that failures are reported as soon as possible to our technical support team at the email address provided below:

sievers.techsupport@veolia.com

We are continually working to make our process and products more robust from our suppliers to your final TOC measurement. Sievers is committed to providing the highest quality products, service, and unmatched support at our ISO 9001, ISO 17025 and ISO 17034 Accredited facilities in Boulder, Colorado and Tatabanya, Hungary.

Completed by: _____ Consumables Lead Quality Engineer Date: 10/13/2023