Pipetting

Trace metal extractables of Finntip and Finntip Flex pipette tips

The values indicated are derived by quantifying the elemental extractables of the Thermo Scientific™ Finntip™ and Finntip™ Flex pipette tips. All analyses were performed by Thermo Fisher Scientific in an ISO 13485:2016 certified facility. The report shows typical trace metal values obtained from a single study and therefore does not guarantee the results for each lot. Severe extraction conditions were used to obtain the maximum extractable limits, and such conditions are considered to be beyond the scope of routine laboratory usage.

Table 1. Trace metal release (in ng/µL) from Finntip and Finntip Flex tips.

Volume	Al	Cd	Cr	Cu	Hg	Fe	Mn	Ni	Pb	Zn
Finntip tips										
0.2–10 µL	<0.001	<0.0000002	<0.002	<0.2	<0.0000007	<0.08	<0.0000007	<0.008	<0.0000008	<0.2
0.5–20 µL	<0.0009	<0.00005	<0.002	<0.05	<0.0000006	<0.03	<0.0000006	<0.000007	<0.0000007	<0.2
0.2–50 µL	<0.0007	<0.00004	<0.002	<0.04	<0.0000005	<0.02	<0.0000005	<0.000006	<0.0000006	<0.2
0.5–250 µL*	<0.0004	<0.00002	<0.0006	<0.02	<0.0000003	<0.01	<0.0000003	<0.000003	<0.0000003	<0.07
5–200 µL (extended length)*	<0.0004	<0.00000005	<0.0005	<0.06	<0.0000003	<0.04	<0.0000003	<0.003	<0.0000003	<0.06
5–300 µL	<0.0003	<0.00002	<0.0005	<0.02	<0.0000002	<0.009	<0.0000003	<0.000003	<0.0000003	<0.06
10–1,000 µL	<0.0002	<0.00001	<0.0004	<0.01	<0.0000002	<0.006	<0.0000002	<0.000002	<0.0000002	<0.04
100–1,000 µL (extended length)	<0.0003	<0.00002	<0.0004	<0.02	<0.0000002	<0.007	<0.0000002	<0.000002	<0.0000002	<0.05
0.5–5 mL	<0.0002	<0.000007	<0.0003	<0.007	<0.00000009	<0.004	<0.00000009	<0.000002	<0.0000001	<0.03
1–10 mL	<0.00009	<0.000005	<0.0002	<0.005	<0.00000006	<0.003	<0.00000007	<0.0000008	<0.00000007	<0.02
Finntip Flex tips										
0.2–10 µL	<0.001	<0.00005	<0.002	<0.06	<0.0000007	<0.03	<0.0000008	<0.000009	<0.0000008	<0.2
1–200 µL (wide)	<0.0004	<0.00002	<0.0007	<0.02	<0.0000003	<0.02	<0.0000003	<0.000004	<0.0000003	<0.07
5–300 µL	<0.0004	<0.00002	<0.0006	<0.02	<0.0000003	<0.01	<0.0000003	<0.000003	<0.0000003	<0.07
10–1,000 µL	<0.0003	<0.00002	<0.0004	<0.02	<0.0000002	<0.006	<0.0000002	<0.000002	<0.0000002	<0.04
50–1,200 µL	<0.0002	<0.00001	<0.0004	<0.02	<0.0000002	<0.006	<0.0000002	<0.000002	<0.0000002	<0.04
1–10 mL (extended length)	<0.0002	<0.000007	<0.0003	<0.007	<0.00000009	<0.004	<0.0000001	<0.000002	<0.0000001	<0.03

* Indicates the products tested. The trace metal values for all other tip volumes were calculated based on the surface areas of those tips.

Table 2. Assay analysis limits.

Assay analysis limits	Al	Cd	Cr	Cu	Hg	Fe	Mn	Ni	Pb	Zn
LOD	0.00000299	0.0000000004	0.00000001	0.00000006	0.0000000020	0.00000561	0.000000002	0.00000003	0.0000000023	0.00001694
LOQ	0.00000906	0.0000000011	0.00000002	0.00000017	0.00000001	0.00001701	0.00000001	0.00000008	0.00000001	0.00005133

The reported values are averages from triplicate samples analyzed for each product type.

Sterilization processes can introduce additional stressors, resulting in sterile products having the highest trace metal levels. Sterilization is not expected to reduce extractables; therefore, all trace metal testing was conducted on sterile products, as they potentially have the same or higher levels of trace metal extractables compared to nonsterile products.

Testing method

The pipette tips were halved lengthwise and placed in clean, dry 15 mL centrifuge tubes that had been acid washed. For each tip type, three individual tips were tested. Concentrated nitric acid (65%, 2 mL) was added to the tubes, which were then sealed with a closure lid. The tubes were laid horizontally flat on an orbital shaker for 1 hour at ambient temperature (20–22°C), with constant agitation to continuously cover the tips with the concentrated acid. The eluate from the tubes was then diluted with ultra trace elemental analysis grade–water in a new 15 mL tube (1:50 dilution; 0.2 mL of eluate with 9.8 mL of diluent) and analyzed by inductively coupled plasma mass spectrometry (ICP-MS). Analyses were performed for all of the trace metals listed in the tables. The limit of detection (LOD) and limit of quantification (LOQ) were determined following published guidance [1]. For results greater than the LOQ, the concentration values were determined. These values were used to calculate the amounts of trace metal released from tips of all volumes in the Finntip portfolio, based on the surface area of the tip, the concentration of the element, and the maximum fill volume of the tip.

Reference

1. US FDA (2021) Q2(R1) Validation of Analytical Procedures: Text and Methodology Guidance for Industry.

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