

Frascati (Rome) – Italy,

Jan 22, 2025

To: Whom it may concern

Subject: Identification and Certification of Biocapt® Single-Use lots

Dear Customer,

Particle Measuring Systems hereby declares that the Certificate of Analysis (CoA) issued with each lot of Biocapt Single-Use is representative of the entire lot, consisting of several sub-lots. The Lot and sublots are identified on each BioCapt Single-Use. The subplot is on the label as shown in Figure #1.



Figure #1

For different sub-lots, which have received the same gamma irradiation treatment, Particle Measuring Systems provides with a CoA data collected from the lot. For each parameter analyzed in the CoA, the data point listed is the data from the individual sub-lot with the worst data. All the other sub-lots performed as well or better than the data reported in the CoA.

To facilitate the identification of the sub-lots, starting from Jul 2024, this reference has also been added to the label affixed to the cardboard box (lot number followed by the sub-lot number separated by “-”) as per below Figure #2



Figure #2

In the event that a sub-lot is subjected to a different irradiation treatment than the rest of the lot, a specific CoA will be issued bearing the indication of the reference sub-lot, as shown in Figure #3 below.

 <b>SYSTEMS®</b> a spectris company			 <b>transparency • safety • people</b>
<b>CERTIFICATE OF ANALYSIS</b>			
<b>MODEL:</b> BioCapt® Single-Use Sampler (*)	<b>PRODUCT CODE:</b> 79001209	<b>BATCH:</b> 24G2901-01	

Figure #3

The Particle Measuring Systems Quality Assurance Department is available for any clarifications needed.

Sincerely,

Particle Measuring Systems S.r.l.

Anna Maria Motti

Quality Assurance Manager

