Cytiva
925 West 1800 South
Logan, Utah 84321
USA

To whom it may concern

Regarding: Melamine contamination in cell culture products

A guidance document entitled Pharmaceutical Components at Risk for Melamine Contamination was issued by the US Food and Drug Administration (FDA) on August 6, 2009. This guidance alerted pharmaceutical manufacturers of finished products, pharmacy compounders, re-packers, and suppliers to the potential risk of melamine contamination in pharmaceutical components.

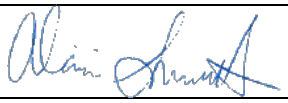
To comply with the FDA guidelines for pharmaceutical components at risk for melamine contamination, Cytiva has reviewed all chemical components that might be included in cell culture products against the guidance. Suppliers of at-risk components have been asked to provide lot by lot assay results for melamine per the FDA guidance, with the expectation that results for each lot will be reviewed by Quality Control (QC) at component incoming inspection.

Specifications for at-risk components require that lot by lot test results are supplied by the supplier or that testing is coordinated by QC prior to component acceptance and release.

The laboratory performing melamine testing has been successfully audited.

Serum does not meet the requirements of an at-risk component for melamine contamination per the FDA Guideline.

We request customers inspect product for damage or evidence of tampering when they receive the product at their site.

Signature: 	Date: 22 Jul 2020
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