EuroSciCon

10th Edition of International Conference on

Analytical Chemistry

February 28-March 01, 2019
London, UK

Insights Anal Electrochem 2019, Volume 5
DOI: 10.21767/2470-9867-C1-009

Novel matrix for immunoassay calibrators and controls

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Manufacturers of immunodiagnostic kits, instruments reagents, etc. have regulatory requirements that involve providing control materials to the end user that will assure consistently precise and accurate potential results. Calibrators also sometimes refer as standards and controls with long term, preferably stable at ambient temperature and appropriate but accurate concentration of analytes and accurate assignment and target values are absolutely critical for this purpose. Unfortunately, even though calibrators prepared from human sources, lot to lot variation in their makeup make it very difficult if not impossible to make them behave as patient samples. These variations or properties are sometimes referred to as matrix effects. Since non-isotopic immunoassay introduced in the early 70s, a number of manufacturers have made several attempts to manufacture or synthesize various matrices that includes human blood, animal serum and other endogenous or non-endogenous proteins or protein-like substances in various configurations to mimic human serum. Although some manufacturers were able to synthesize formulation that works well for one or two analytes, they were unable to make universal "cocktail" which could be substituted as "matrix solution." In addition, they encountered another problem associated with protein based calibrators. Our study with synthetic matrix revealed that even most sensitive proteins can be stabilized at ambient temperature for over twelve months without the need of refrigeration or lyophilization.

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