

New international reference preparation for proteins in human serum (RPPHS)

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Abstract

Quality-control surveys in recent years, in various parts of the world, have shown poor between-laboratory agreement for measurements of plasma proteins. Despite the existence of international reference materials distributed by the World Health Organization, standards produced by diagnostics manufacturers and professional organizations differ significantly in their ascribed values. The reasons for this are complex but include poor availability of the primary materials, confusion about their use, and the fact that their turbidity on reconstitution precludes their use in modern optical immunoassays. This unfortunate situation led to an important initiative to produce sufficient quantities of a widely available, optically clear secondary reference material for plasma proteins that could be used worldwide by manufacturers, professional organizations, and laboratories. Here we present an overview on how the laboratory community, including manufacturers, clinical laboratories, professional societies, and regulators, has reached what we consider is a successful conclusion to a difficult problem.

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