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Anti-D (Rh₀) Reagent:

The reagent can be monoclonal or polyclonal and must be obtained from manufacturers or suppliers licensed by the Center for Biologics Evaluation and Research, Food and Drug Administration for use in microplate tests. The use of reagents from an unlicensed manufacturer or supplier may invalidate the results. Note that this reagent is different from Anti-D Reagent. Consult manufacturer's package insert to ensure that it is Anti-D (Rh₀) Reagent and not Anti-D Reagent.

[NOTE—There are many manufacturers and suppliers of these reagents that are licensed by the Center for Biologics Evaluation and Research, Food and Drug Administration. Some examples of licensed manufacturers or suppliers are the following: Gamma Biologics, Houston, TX; and Ortho Diagnostics, Raritan, NJ.]

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ANTI-D (RHO) REAGENT	Margareth R.C. Marques Principal Scientific Liaison	HDQ Headquarters

Most Recently Appeared In:
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