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2nd WHO INTERNATIONAL STANDARD FOR ANTI-D IMMUNOGLOBULIN

Report of The International Collaborative Study to Calibrate a Proposed Global (WHO International/US/Ph Eur) Standard For Anti-D Immunoglobulin

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1. Summary

The candidate Global (ie WHO International/US/Ph Eur) Standard for anti-D immunoglobulin, human (01/572), was evaluated and calibrated against the WHO International Reference Preparation for anti-D immunoglobulin, human (68/419), along with two reserve candidate Biological Reference Preparations (BR in an international collaborative study involving 25 laboratories in 15 countries. The current US-FDA Standard for anti-D immunoglobulin, lot 3, was also included for comparison. Most laboratories (20/25) performed AutoAnalyzer methodology, competitive EIA and/or flow cytometry.

The overall mean potency (from all methods) of the candidate Global Standard, 01/572, was 284.5 IU/ampoule, with an inter-laboratory variation, expressed as % gcv, of 9.7%. The mean potencies of the two candidate reserve BRPs (from all methods) were 110.6 IU/ampoule and 105.7 IU/vial with inter-laboratory variability, expressed as %gcv, of 9.6%

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