

Response to Comments Received to the 4th edition of Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens.

Please note that public comments that were submitted address the proposed 4th edition of MT Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The program unit has elected to make the substance of public comments that were submitted a part of this document. This document does not represent a full summary of significant changes to the 4th edition of MT Standards. Guidance that appears with the 4th edition of MT Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	Comment	Change made?	Outcome
Reference Standard 2.2A, RH line	<p>RHD target nucleotide: exons 4&7 associated with phenotype D+/-.</p> <p>Proposed change on target nucleotide: “at least two exons”.</p> <p>References:</p> <p>Doescher et al. Evaluation of single-nucleotide polymorphisms as internal control in prenatal diagnosis of fetal blood groups. Transfusion, 2013 Volume 53, pag 353-362.</p> <p>De Haas M. et al. Sensitivity of fetal RHD screening for safe guidance of targeted anti-D immunoglobulin prophylaxis: prospective cohort study of a nationwide programme in the Netherlands. BMJ 2016;355:i5789.</p> <p>Ziza et al. Determination of Fetal RHD Genotype Including the RHD Pseudogene in Maternal Plasma. Journal of Clinical Laboratory Analysis 00: 1–6 (2016)</p>	No	The committee did not feel that this change was appropriate at this time. The committee purposefully maintained the 4 and 7 nucleotides as they are robust and allowing any two could be less successful.
Reference Standard 2.2A, RH line	RHD psi target nucleotide: 37 bp insert in exon 4. Proposed change on target nucleotide: “37 bp insert in exon 4 or RHD c.807T>G”.	Yes	The committee notes this comment and agreed to add the variant of “or RHD c.807T>G” to the <i>RHDΨ</i> gene entry based on the study cited in the comment.

	<p>Reference: http://www.rhesusbase.info/</p> <p>RHCE proposed change: add the polymorphism RHCE c. 712A>G for phenotype V/VS</p> <p>Reference: Hemker MB, et al. DAR, a new RhD variant involving exons 4, 5 and 7, often in linkage with ceAR, a new Rhce variant frequently found in African blacks. <i>Blood</i>, 1999 volume 15:94(12): 4337-42.</p> <p>Human Blood Groups. Daniels G. Third edition, Wiley-Blackwell, 2013.</p> <p>The Blood Group Antigen (Facts Book). M. Reid, C. Lomas-Francis and M.L. Olsson. Third edition Elsevier, 2013.</p>		
Reference Standard 2.2A, JK line	Why were the JK comments, recommendation of testing for Jk nulls eliminated?	No	The committee noted this comment but felt that the entry was not a standard and would better fit in guidance. The committee felt that this was important to remove for consistency and that individuals were reading this as a requirement, and not as assistance.