Product specification and information

IRM 926 - Hev b 6.02 Reference Protein

1. Name of material — Hev b 6.02 protein reference antigen

2. IRM Number/ Lot Number — IRM 926/ Lot TK01-06

3. Organization preparing the material — Icosagen AS (former Quattromed), Estonia

4. Antigen Specification

Table 1
Specification for Hev b 6.02 antigen

Property	**ASTM Designation**	**Limits/Targets**
Source	D-7427, D 5900	Natural Rubber Latex
Protein amount	D-7427, D 5900	Stock solution should be adjusted to 200 ng/mL
Form		Lyophilized, white to off-white powder
RP chromatography profile	D-7427, D 5900	One major peak detectable
Mass spectrometry profile	D-7427, D 5900	One major peak detectable at molecular weight 4-5 kDa
Capture ELISA reactivity	D-7427, D 5900	Adjust antigen content based on D-7427 determination

5. Specific conditions under which the IRM is to be stored

The material is stored lyophilized in glass vials at 4ºC. The shelf life of the product has not been determined but shelf life is well established for other lyophilized proteins. The reagent should have a minimum shelf life of 10 years provided that the 4ºC conditions are maintained. To ensure Hev b 6.02 antigen quality, it should be tested for its reactivity in the IEMA assay every 24 month to ensure that degradation has not occurred.

6. Specific steps before taking IRM into use

Reconstitute the lyophilized material with 612µL distilled water, mix thoroughly. As a result the protein concentration in vial is 200 ng/mL.

Dilute reconstituted IRM solution (200 ng/mL) into reference material buffer (100mM MES, 10mM EDTA, 0.5%BPLA, 0.5% Tween20, 0.5% Dextran T-500, 0.02% Gentamycin, 0.09% NaN3, pH 6.0) in order to get at least 5 different concentration points distributed evenly over the working range of the Hev b 6.02 IEMA (0 ng/mL to 200 ng/mL). Store solutions as aliquots in polypropylene tubes at -20oC, if needed. Avoid repeated freeze thaw cycles.

7. Working calibrator validation using IRM

Calibrators should be prepared and used instead of reference antigen (IRM) to construct standard curves in the immunoenzymetric assay (IEMA). These calibrators must, however, meet the criteria described in D-7427 Section 8.8.1.2 or commercially-available liquid calibrators described in Section 8.8.1.1. should be used. The working calibrator must be cross-validated against its appropriate reference antigen IRM. Cross calibration (cross-validation) should be performed using the procedure provided in D-7427 Section 11.2.

8. Other information

To verify the specificity and immunoreactivity of the Hev b 6.02 protein (IRM 926), anti-Hev b 6.02 capture antibody (IRM 924) and anti-Hev b 6.02 detection antibody (IRM 925) that are used together to perform the Hev b 6.02 IEMA.

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