

Anti-Rods/Rings antibody (anti-RR) Reference Material for ICAP Pattern AC-23

Product Package Insert

Catalogue IS2725

Lot 07800

DOM: Aug 2017

Intended Use: For *in vitro* immunodiagnostic use as a human reference standard having high levels of antibodies to rods/rings and be used to confirm the specificity of local standards.

Description of Reference Material: Defibrinated human plasma from a single donor was donated by Plasma Services Group Inc. (PSG) in Huntingdon Valley, PA. Volumes of 200 μ L were dispensed into borosilicate glass vials, freeze-dried, and sealed with butyl rubber stoppers while still under reduced pressure. Vials are stored at PSG at -20°C and delivered directly to users from PSG.

Reconstitution and Storage: Store the freeze-dried material at -20°C until use. To reconstitute, the contents should first be shaken to the bottom by tapping the upper end or by gently tapping the bottom of the vial on the lab bench. Before the stopper is removed, the vacuum should be broken by insertion of a hypodermic needle through the rubber stopper. Precisely 200 μ L of distilled water should then be added, and the vial re-stoppered. The freeze-dried powder should dissolve readily with gentle swirling (avoid foam). Allow to stand for at least 1 h before use and store at 4°C if planning to use within 24 h. Otherwise, the reconstituted standard can be aliquoted and stored at -20°C or lower for later use.

Caution: This material was tested and found negative or non-reactive for STS, HBsAg, HIV 1 Ag (or HIV PCR (NAT)), HCV antibody, HCV PCR (NAT) and HIV1/2 antibody as required at the time of bleeding using FDA-licensed test kits. Since no method can offer complete assurance that these or other infectious agents are absent, this reference material should be handled as if capable of transmitting infection.

Anti-Rods/Rings Antibody Content: This human reference material contains antibodies to rods/rings structures clearly seen in the cytoplasm^{1,2} but also reported in the nucleus³. This reference material reacts strongly with inosine monophosphate dehydrogenase (IMPDH). Eight international laboratories confirmed the specificity of this reference material. Methods used include indirect immunofluorescence (IF), immunoprecipitation (IP), IP-western blotting, line immunoassay (LIA), and addressable laser bead immunoassay (ALBIA).

TECHNICAL DETAILS & APPLICATIONS

Purification Method: Not purified, defibrinated human plasma

Autoantigen identified: inosine monophosphate dehydrogenase 2 (IMPDH2, NCBI Gene ID 3615); possibly IMPDH1 (Gene ID 3614)

Calculated MW of IMPDH2: 56 kD (514 aa)

Observed MW of IMPDH2: 56 kD

Storage: After reconstitution in 200 μ L water as described above, store at -20°C or lower.

Storage Buffer: The reference material contains 4% Na Citrate as an anticoagulant. No preservatives have been added.

Tested Applications: IF, IP, IP-western blotting, LIA, and ALBIA. Note that this reference material does not recognize IMPDH in typical western blotting.

Known Species Specificity: Human

Tested Species: Human

Recommended Dilutions:

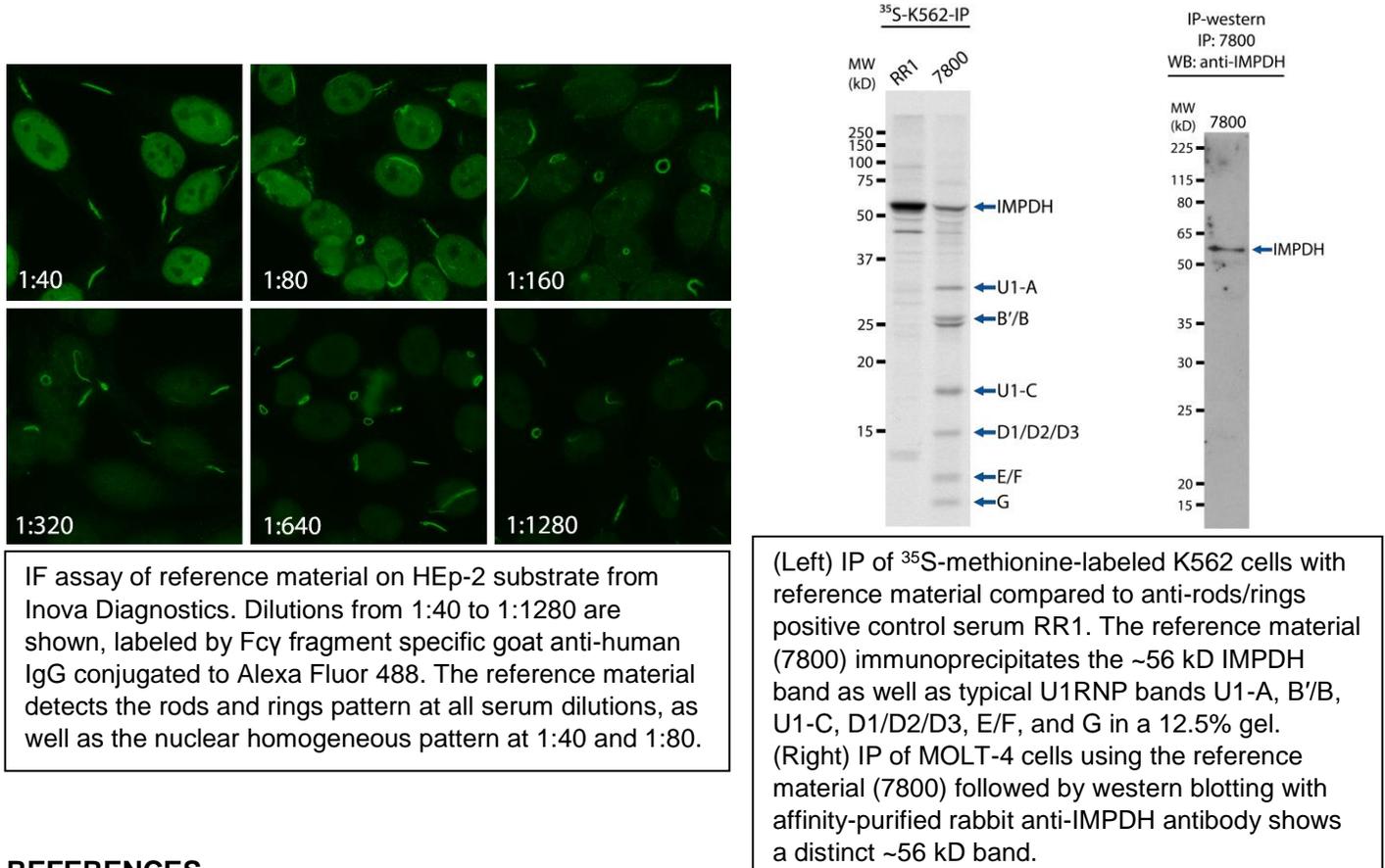
IF on HEp-2: Starting dilution 1:80, positive to at least 1:1280

IP: undiluted (use 8 μ L reference material)

Notes: In addition to the rods and rings pattern (AC-23), this reference material also shows a nuclear homogenous pattern (AC-1) by IF. This pattern may serve as an internal positive control for detection of anti-rods/rings autoantibody, as rods and rings structures appear in cells only under certain culture conditions^{1,4-6}. To date, HEp-2 slides from Inova Diagnostics (San Diego, CA) and Euroimmun GmbH (Luebeck, Germany)

consistently detect anti-rods/rings. Substrates from other commercial sources are not currently recommended for detection of anti-rods/rings in human sera. The rods and rings pattern was positively detected in this reference material by all reference laboratories using HEp-2 substrate from Inova Diagnostics. With this reference material, positive detection of AC-1 but not AC-23 by IF indicates that rods and rings structures are not present in the substrate, and that another substrate should be used. If both AC-1 and AC-23 are negative, this would indicate a potential protocol or performance error in the used by the testing laboratory.

VALIDATION DATA



REFERENCES

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