# Rubella IgM Hybrid Human Monoclonal Antibody, Code BM 1361, Clone 1412010

Characterized disease state sera are critical components in the development and manufacture of diagnostic tests. However, sourcing of these sera is complicated, time-consuming and sometimes suitable material is not available at all. In the case of Rubella IgM most people are vaccinated at a young age and, as such, souring of natural high titer Rubella IgM plasma/serum is becoming ever more challenging. Aalto Bio Reagents offers Rubella IgM hybrid human monoclonal antibody (code BM 1361) as an alternative.

This monoclonal antibody has been produced in mice genetically modified to express human IgM heavy chain constant region. The mice were immunised with native Rubella virus antigen from strain HPV-77. This is the virus strain that is used by most Rubella assay manufactures.

The high specificity of the antibody is demonstrated by Western Blot. Native Rubella Virus antigen from strain HPV-77 was subjected to electrophoresis followed by immunodetection using the Rubella IgM Hybrid Human Monoclonal Antibody, Code BM 1361 (Figure 1).

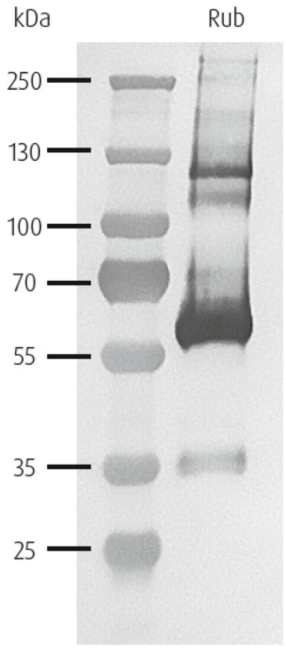


Figure 1: Rubella antigen detection using BM 1361 by Western Blot.

## Analysis

As part of the selection process multiple clones were analysed by both in-house ELISA (Figure 2, Table 1) and using commercially available Rubella IgM ELISA and CHLIA assays (further details available on request). The clone with the most reactivity was selected for commercialisation, clone 1412010. According to in-house ELISA analysis the antibody shows OD values clearly above the positive control serum and a high lot- to-lot consistency.

## Presentation

This Rubella IgM monoclonal antibody is purified from the cell culture supernatant by a proprietary technique. This process removes all but trace amounts of the animal derived additive that is used as a growth medium in the cell culture supernatant. The antibody is concentrated in the range of 100 – 150 ug/ml and spiked into an IgG depleted and delipidised human serum matrix. This presentation ensures that the final product is as close as possible to natural Rubella IgM positive human serum.

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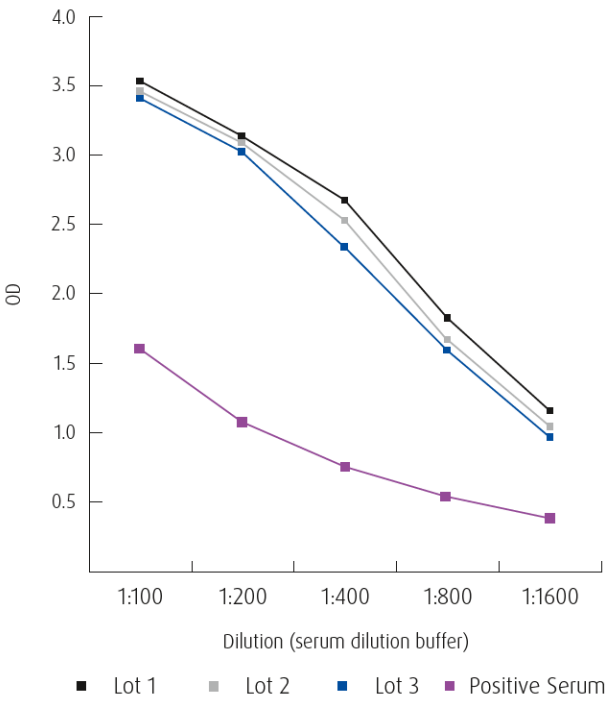
Table 1

| | Dilution | MV OD | U/mL |
|---|---|---|---|
| | STD | 0.765 | 13.6 |
| | NC | 0.144 | < 2 |
| Lot 1 | 1:100 | 3.548 | > 120 |
| | 1:200 | 3.313 | > 120 |
| | 1:400 | 2.720 | > 120 |
| | 1:800 | 1.876 | 59.7 |
| | 1:1600 | 1.176 | 24.8 |
| Lot 2 | 1:100 | 3.466 | > 120 |
| | 1:200 | 3.189 | > 120 |
| | 1:400 | 2.549 | > 120 |
| | 1:800 | 1.689 | 47.3 |
| | 1:1600 | 1.052 | 21.0 |
| Lot 3 | 1:100 | 3.419 | > 120 |
| | 1:200 | 3.091 | > 120 |
| | 1:400 | 2.387 | > 120 |
| | 1:800 | 1.585 | 41.6 |
| | 1:1600 | 0.918 | 17.3 |
| Positive Control Serum | 1:100 | 1.638 | 44.4 |
| | 1:200 | 1.149 | 24.0 |
| | 1:400 | 0.789 | 14.2 |
| | 1:800 | 0.510 | 8.4 |
| | 1:1600 | 0.324 | 5.1 |

Figure 2




## About Aalto Bio Reagents

Founded in 1978, Aalto Bio Reagents is a leading developer and provider of raw materials to the in- vitro diagnostics industry and to research laboratories globally. We serve the largest multinational companies in our industry with a broad range of purified human proteins; monoclonal and polyclonal antibodies; fungal, parasitic, bacterial and viral antigens; and disease state plasma for in- vitro diagnostic application.

Since the company's inception, we have built strong working relationships with our clients who trust us to provide them with the highest quality raw materials to meet the exacting standards of their own product development requirements. We are certified to ISO 13485:2016. Headquartered in Dublin, Ireland, the company is rapidly expanding both its product portfolio and customer base.

For further information please visit our website at www.aaltobioreagents.com or contact us at info@aaltobioreagents.com.

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