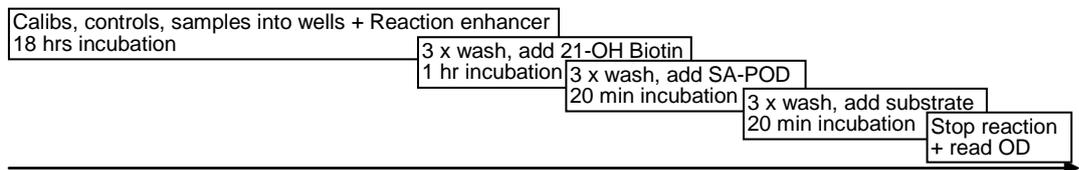


- Description:** Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to steroid 21-hydroxylase (21-OH) in serum
- Disease application:** Addison's disease
Addison's disease in Autoimmune Polyglandular Syndromes (APS) Type I or II
- Test samples:** Sera can be used. Do not use lipaemic or haemolysed serum samples or plasma samples. No interference was observed with bilirubin at 20 mg/dL, haemoglobin at 500 mg/dL, intralipid up to 3,000 mg/dL.
- Assay volume:** 50µL per well
- Total assay time:** Approx. 20 hours
- Assay method:**



- Sensitivity:** 81% n = 63 for Addison's disease patients
- Specificity:** 99.5% n = 211 for healthy blood donors
The healthy blood donor serum that was 21-OH Ab positive was also positive in RiaRSR™ 21-OH Ab when anti-human IgM-agarose was used instead of protein A.
- Calibrator range:** 0.3 - 100 units/mL (arbitrary RSR units)
- Reference cut-off:** Negative: <0.4 units/mL; Positive: ≥0.4 units/mL
- Advantages:** A non-isotopic method easy to use in routine clinical laboratories and suitable for automated systems. It offers even higher disease specificity and sensitivity than RiaRSR™ 21-OH Ab.
- Features:** Reliable and convenient method to measure specific 21-OH autoantibodies, which are a major component of adrenal cortex antibodies (ACA), in autoimmune adrenal disease.
- Improvements:** Both sensitivity and specificity have been improved (compared with RiaRSR™ 21-OH Ab).
- Kit size:** 96 wells
- Order code:** 21E/96
- Literature:**
J Furmaniak and B. Rees Smith, J Clin Endocrinol Metab 1995 **80**: 1502-1505
Editorial: Adrenal and gonadal autoimmune diseases
S Chen et al, J Clin Endocrinol Metab 1996 **81**: 1871-1876
Autoantibodies to steroidogenic enzymes in autoimmune polyglandular syndrome, Addison's disease, and premature ovarian failure
H Tanaka et al, J Clin Endocrinol Metab 1997 **82**: 1440-1446
Steroid 21-Hydroxylase autoantibodies: Measurements with a new immunoprecipitation assay
G Coco et al, J Clin Endocrinol Metab 2006 **91**: 1637-1645
Estimated risk for developing autoimmune Addison's disease in patients with adrenal cortex autoantibodies
E S Husebye et al, J of Internal Medicine 2014 **275**: 104-115
Consensus statement on the diagnosis, treatment and follow-up of patients with primary adrenal insufficiency

This kit is intended for in-vitro use by professional persons only. The data quoted is for guidance only. Each laboratory should establish its own normal and pathological reference ranges for the assay and should include its own panel of control samples in the assay along with the controls provided as part of the kit.

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TECH/ElisaRSR 21-OH Ab Rev1