

Assay Performance Data

Naam assay:	Thyroidperoxidase IgG As [eenheden/volume] in serum of plasma [LOINC 18332-7]
Methode, fabrikant:	Fluorescence Enzyme Immuno Assay (FEIA) – ImmunoCAP Phadia 250, ThermoFisher Scientific

Traceerbaarheid:											
Gekalibreerd naar	Afkomstig uit de bijsluiter: Reference material: The ImmunoCAP Specific IgG Calibrators are traceable (via an unbroken chain of calibrations) to the International Reference Preparation (IRP) 67/86 for Human Serum Immunoglobulins A, G, and M from World Health Organisation (WHO). The calibrators are used for determination of Autoantigen specific IgG antibodies. The values are expressed in mgA/l, where A represents antigen-specific antibodies. By using a conversion factor included in the software, the values are expressed in IU/ml. The conversion factor has been determined by means of NIBSC research standard for anti-thyroid microsome serum code 66/387.										
Referentie-interval of afkapgrenzen (gebruik UCUM-eenheden)											
Herkomst referentiewaarden	Afkomstig van de firma: The ranges (negative, equivocal, positive) recommended for the evaluation of the results are: <table border="1" data-bbox="699 1055 1449 1126"> <thead> <tr> <th>Test</th> <th>Unit</th> <th>negative</th> <th>equivocal</th> <th>positive</th> </tr> </thead> <tbody> <tr> <td>EliA TPO</td> <td>EliA U/mL</td> <td><25</td> <td>25 -35</td> <td>>35</td> </tr> </tbody> </table>	Test	Unit	negative	equivocal	positive	EliA TPO	EliA U/mL	<25	25 -35	>35
Test	Unit	negative	equivocal	positive							
EliA TPO	EliA U/mL	<25	25 -35	>35							
Stabiliteit monster											
Kamertemperatuur 4 °C -20 °C	Ja/Nee*, termijn: 2 dagen Ja/Nee*, termijn: 2 weken Ja/Nee*, termijn: 12 maanden										
Detectielimieten (gebruik UCUM-eenheden)											
LoD (Limit of Detection) LoQ (Limit of Quantitation)	N.v.t. bij autoantistofbepalingen										
Imprecisie (gebruik UCUM-eenheden)											
Concentratie (level invullen)	Level interne controle: 278 mg/L, CV (%): 8,8%										
Meetbereik (gebruik UCUM-eenheden)											
Meetbereik	4 – 1542 IU/mL										
Extern QC programma											
(Inter)nationaal extern QC programma Indien niet beschikbaar, alternatieve aanpak	SKML-HIM Schildklier antistoffen										

* Doorhalen wat niet van toepassing is.

Ingevuld door: Caroline Roozendaal	Datum: 1-5-2019
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