

Lab Handbook Change Request and Blood Science Analyte (Test) Proforma

Total IgE - proposed update to published Lab Handbook reference intervals, related test link and interpretative comment
Purpose: request LCL IT/Lab Handbook update for Total IgE content on the Immunology Lab Handbook pages, with controlled verification before publication.

Field	Detail
Test Name (Analyte)	Total IgE
Alternative Name(s) and Keywords	Immunoglobulin E; IgE; Total Immunoglobulin E; Serum IgE; allergy; atopy; serum gel.
Discipline/Specialty	Immunology.
Description	Total IgE measures the total concentration of immunoglobulin E in serum. It is used as a supportive laboratory marker in the assessment of suspected IgE-mediated allergic disease and atopy. Total IgE is not diagnostic of allergy in isolation and should be interpreted with clinical history and, where appropriate, allergen-specific IgE results.
Clinical Indication	Supportive investigation for suspected type I immediate hypersensitivity, atopy and related allergic conditions. Where a specific allergen is clinically suspected, request Allergen-specific IgE guided by the clinical history. Avoid non-specific or blanket allergen screening. Clinical interpretation should consider age-related reference intervals and relevant clinical features.
Patient Preparation	No specific patient preparation required. Clinical details should include relevant allergic symptoms, suspected allergen exposure, eczema/asthma history or other relevant clinical context where available.
Specimen Container	Serum Gel tube, gold top, as currently stated on the Total IgE Lab Handbook page.
Container Image	Retain current Serum Gel / gold top container image already shown on the Total IgE Lab Handbook page. No new container image requested.
Primary Sample Type	Serum.
Minimum Volume Required (μ L for serum//blood/urine etc. unless otherwise stated)	Current published Lab Handbook wording states 5 mL. Confirm minimum analytical volume against the current analytical SOP and platform dead volume requirements before publication. If no change is approved, retain 5 mL.
Special Precautions / Requirements	None beyond standard patient identification, specimen labelling and safe blood collection requirements. Ensure the request is for Total IgE and not Allergen-specific IgE unless specific allergens are required.
Transport and Storage Requirements	Transport to the laboratory using standard serum sample transport arrangements. Confirm any stability, storage or refrigeration requirements against the current analytical SOP before publication.
Telepath Test Code	IGE / Total IgE. Confirm exact Telepath mnemonic with LCL IT before publication and ensure the Lab Handbook wording matches the LIMS build.
National Pathology Code (READ/SNOMED CT)	To be supplied or confirmed by LCL IT if required.

Doc. No:	IT-FOR-2	Approved by:	Heather Clucas / Joe Taylor
Author:	Sarah Curtis	Page 1 of 3	Last printed 21/05/2026 10:28

Reference Interval(s)	<p>Replace the current single Total IgE reference range with the following age-related reference intervals. Unit: kU/L.</p> <p>Age at specimen collection date: Less than 3 months: 0 - 4 kU/L 3 - 12 months: 0 - 13 kU/L 1 - 5 years: 1 - 48 kU/L 5 - 10 years: 1 - 85 kU/L 10 - 15 years: 1 - 155 kU/L 15+ years: 1 - 113 kU/L</p> <p>Age boundary note: reference interval selection should be based on age at the specimen collection date. The upper boundary of each age range should be treated as inclusive, with the next age band commencing the following day.</p>
Telephone Action Limit(s)	No telephone action limit proposed for Total IgE. Confirm against the current analytical SOP and local clinical action limit policy.
Measurement Units	kU/L.
Clinical Interpretation	<p>Add the following Lab Handbook / report comment for Total IgE results >200 kU/L, subject to clinical authorisation before release:</p> <p>For Total IgE >200 kU/L: Raised Total IgE may be seen in atopic or allergic disease, parasitic infection, allergic bronchopulmonary aspergillosis, some immunodeficiency syndromes and other inflammatory conditions. Total IgE alone is not diagnostic of allergy. If immediate hypersensitivity is suspected, consider Allergen-specific IgE testing guided by the clinical history.</p> <p>Add a cross-reference on the Total IgE page to Allergen-specific IgE.</p>
Useful Links / Guidelines	<p>Current Total IgE page: https://pathlabs.rlbuht.nhs.uk/totalige__i.htm Related test page to add as link: Allergen-specific IgE, https://pathlabs.rlbuht.nhs.uk/allergenspecificige__i.htm Advice on the use and interpretation of Immunology laboratory tests: https://pathlabs.rlbuht.nhs.uk/immunology_handbook.pdf Consider also updating the IgE section on the Immunoglobulin Analysis page if it remains a live source of IgE reference range information, to avoid conflicting Lab Handbook information.</p>
Common Interferences / Causes of Spurious Results	Confirm platform-specific interferences in the current analytical SOP and reagent IFU. General risks include insufficient volume, incorrect sample type, severe sample quality issues, mislabelling and inappropriate requesting without relevant clinical history.
Availability of Clinical Advice	For Clinical queries please email: Allergy.Immunology@liverpoolft.nhs.uk and for other lab related queries email ImmunologyQueries@liverpoolft.nhs.uk
Significant Change Values	Not applicable / not established for routine Lab Handbook use unless defined in the analytical SOP.
Testing Frequency / Minimum Re-testing Interval	No fixed minimum re-testing interval proposed. Repeat testing should be clinically justified and interpreted in clinical context.

Related tests	Allergen-specific IgE. Mast Cell Tryptase may be relevant where anaphylaxis is suspected. Total immunoglobulins may be relevant where immunodeficiency or immune dysregulation is suspected.
Technology & Analytical Principle Used	Fluorescent enzyme immunoassay, as currently stated in the Immunoglobulin Analysis Lab Handbook content. Confirm current platform and method against the analytical SOP before final publication.
EQA Scheme	Confirm against current Immunology EQA records before publication. Record EQA provider and scheme name in the final controlled version if required by the Lab Handbook process.
Laboratory Performed	Liverpool Clinical Laboratories - Immunology. Confirm performing site before publication if site-specific information is required.
UKAS Accreditation Status	Confirm current UKAS schedule/accreditation status for Total IgE before publication. Do not state UKAS accreditation unless confirmed against the current scope.

Form completed by: Immunology Manager / Medelyn Lapitan

Date: 21/05/2026

Change control completed by: [insert change control reference / approver]
(QMS-EXTD-160, LCL Laboratory Handbook)

Date: [insert date]