LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human serum and plasma.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

BIBLIOGRAPHY

1. The biology of IGE and the basis of allergic disease. Annu Rev Immunol. 2003; 21: 579–628.
2. IgE concentrations measured by PRIST in serum of healthy adults and in patients with respiratory allergy. A diagnostic approach". Allergy. 1981;36(8):537-547
3. Allergen drives class switching to IgE in the nasal mucosa in allergic rhinitis. J Immunol. 2005; 174(8): 5024–5032

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	Use by
Contains sufficient for <n> tests	REF Catalogue Number	LOT Batch Number / Lot Number	DEVICE Device

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

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0323/VER-01

FIAcheck™

IgE

Fluorescence Immunoassay for Quantitative determination of Immunoglobulin E (IgE) concentration in Human Serum and Plasma

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ IgE Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of Immunoglobulin E (IgE) concentration in Human Serum and Plasma.

INTRODUCTION

IgE is also known as the reagenic antibody. In general, elevated levels of IgE indicate an increased probability of an IgE-mediated hypersensitivity, responsible for allergic reactions. Parasitic infestations such as hookworm and certain clinical disorders including aspergillosis, have also been demonstrated to cause high levels of IgE. Decreased levels of IgE are found in cases of hypogammaglobulinemia, autoimmune diseases, ulcerative colitis, hepatitis, cancer, and malaria. Cord blood or serum IgE levels may have prognostic value in assessing the risk of future allergic conditions in children. The IgE serum concentration in a patient is dependent on both the extent of the allergic reaction and the number of different allergens to which he is sensitized. Non allergic normal individuals have IgE concentrations that vary widely and increase steadily during childhood, reaching their highest levels at age 15 to 20, and there after remaining constant until about age 60, when they slowly decline. Patients with atopic allergic diseases such as atopic asthma, atopic dermatitis, and hay fever have been shown to exhibit increased total immunoglobulin E (IgE) levels in blood. The IgE Quantitative Enzyme Immunoassay provides a rapid, sensitive, and reliable assay for total serum IgE.

PRINCIPLE OF THE TEST

FIAcheck™ IgE is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ IgE** test device is coated with immobilized IgE mouse monoclonal antibody 1 on the test line, goat anti chicken IgY in control line and a mixture of IgE mouse monoclonal antibody 2 and Chicken IgY labelled with fluorescent microspheres on the binding pad.

IgE in sample binds to the IgE mouse monoclonal antibody 2 labeled with fluorescent microspheres in the binding pad.

The fluorescent labeled Ag-Ab complex move forward due to capillary action and are captured by the immobilized IgE mouse monoclonal antibody 1 forming a double antibody sandwich and produces the test line.Chicken IgY labeled with fluorescent microspheres binds with goat anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

- **FIAcheck™ IgE** test device in a sealed pouch with desiccant.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

Materials required but not provided

- Precision pipettes: 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ IgE** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.

4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

SAMPLE COLLECTION

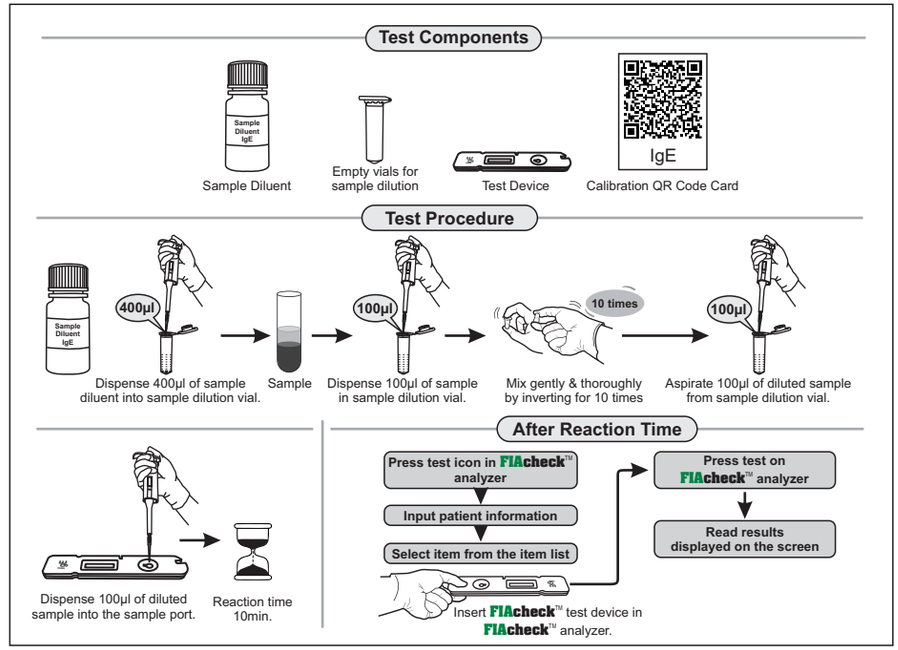
1. Only human Serum/Plasma sample should be used. Other bodily fluids and samples may not give accurate result.
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid grossly hemolytic, lipemic or turbid samples.
5. Preferably use fresh samples. However, samples can be stored for 3 days at 2°C to 8°C, and if more than 3 days, they should be stored at -20°C.
6. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect test values.
7. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Samples should be free from particulate matter and microbial contamination.

PRECAUTIONS

1. Only for In vitro diagnostic use.
2. Bring all reagents and samples to room temperature before use.
3. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
4. Do not reuse the tested **FIAcheck**™ device. Do not use sample dilution vial for more than one sample.
5. Do not use damaged **FIAcheck**™ test device or pouch.
6. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
7. Do not use kit after the expiry date.
8. Do not mix components of one kit with another.
9. Always use new tip for each sample and reagent.
10. Scan QR code card specific to the lot you are using.
11. Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
12. It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
13. It is not recommended to use the sample diluent and sample mixture beyond specified time.
14. The **FIAcheck**™ test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
15. The **FIAcheck**™ test device should be used only in conjunction with **FIAcheck**™ analyzer for accurate and reliable results.

TEST PROCEDURE

1. To calibrate the **FIAcheck**™ **IgE** kit, scan the QR code card provided with the kit.
2. Dispense **400** µl of sample diluent into the empty sample dilution vial.
3. Add **100**µl of the test sample into this sample diluent & mix by rinsing the tip 3 times.
4. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times. (See pictorial representation).
5. Remove **FIAcheck**™ **IgE** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
6. Dispense 100 µl of the above mixture at the sample port in the **FIAcheck**™ **IgE** test device.
7. Incubate at room temperature (18°C to 30°C) for **10 minutes**.
8. After 10 minutes, insert the test device immediately into the **FIAcheck**™ analyzer and read results.



Expected Range
Reference range:
Neonates: 1.5 IU/mL
<1 year: 15 IU/mL
1-5 year: 60 IU/mL
6-9 year: 90 IU/mL
10-15 year: 200 IU/mL
≥15 year: 100 IU/mL
IgE concentration is determined using samples obtained from 300 apparently healthy individuals.
It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 1-2500 IU/mL, r≥0.990.
2. Lower Detection Limit: ≤1 IU/mL.
3. Upper Detection Limit: ≥2500 IU/mL.
4. Accuracy: Verify with comparison experiments, the relative deviation is within ±15%.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIAcheck**™ **IgE** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck**™ **IgE** has demonstrated 100% clinical correlation with the commercially available licensed kit.

IgE Levels	No. of samples	**FIAcheck**™ **IgE**	EIA IgE
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck**™ **IgE** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck**™ **IgE** has demonstrated 100% correlation with the reference method.
*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).