



| Health Technology Review                  |   |
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| <b>Technology Ref.:</b>                   | HTA : 24042                                       |
| <b>Technology Name/Version/Model:</b>     | Food intolerance, IgG using the Food Xplorer kit  |
| <b>Approvals by International Bodies:</b> | Mohap : Registered<br>CE IVD                      |
| <b>Company name:</b>                      | MacroArray Diagnostics (MADx)<br>Country: Austria |
| <b>Agent in UAE:</b>                      | Purelab   |
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| <b>Short Description of the Technology:</b> | <ul style="list-style-type: none"> <li>• The Food Xplorer (FOX) is an Enzyme-Linked Immunosorbent Assay (ELISA) – based in-vitro diagnostic tests for the semi-quantitative measurement of specific immunoglobulin G (IgG). Fox is diagnostic test for the determination of specific immunoglobulin G (IgG) against 286 food antigens.</li> <li>• FOX utilizes food extracts attached to nanoparticles on a solid surface. When patient serum or plasma is introduced, specific IgG antibodies bind to these extracts, and after washing away unbound antibodies, an enzyme-linked detection system generates a measurable signal indicating the level of IgG antibodies present.</li> <li>• Limitations Of The Procedure: Potential safety concerns include False-positive test results may occur due to cross-reactivity of the tested antigen with epitopes of other antigens. Antigenic epitopes may be lost during the production of food extracts, which may lead to false-negative results.</li> <li>• FOX serves as a valuable tool in dietary management and diagnosis of food intolerances, particularly for patients experiencing unexplained symptoms related to food intake. It is recommended to be used alongside professional guidance from healthcare providers for optimal results.</li> <li>• Lab tested comparison have been done with CAP accredited lab : The Fox ELISA method was blind tested with 26 well-characterized sample that included 13 food sources (286 antigens ).These sample were previously tested by CAP accredited Laboratory (PHD,Dubai). The qualitative results had 96.2% agreement between manual assays at PHD and immunology-Union 71 laboratories.</li> </ul> |
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Health Technology Assessment Team Recommendation:

Approve

Summary of Review:

FOX (Food Xplorer) is an ELISA based multiplex food antigen test allowing the simultaneous measurement of specific IgG (sIgG) against a plethora of food extracts and molecular food antigens.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. To be done for patients who have food allergy , or food intolerance.
2. Establishing a proper quality monitoring process and reporting or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

Technology Image





## Population, setting and intended user for Technology “Food intolerance, IgG using the Food Xplorer kit”

- **Population/ Intended User;**
  - Patients who have allergy symptoms but not confirmed yet by lab test
- **To be performed by:**
  - **Trained laboratory technicians / clinical laboratory scientists.**
- **Clinical Setting:**
  - Laboratories, clinics, and hospitals.
- **Condition of use:**
  - Food allergy or food intolerance.
- **Exclusion criteria:**
  - Other conflicting medical issues