How ISO 13485:2016 and ISO 15189 are Revolutionising Lyme Disease Testing

Acceptance of Foreign Test Results

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Disclosure Statement:
I am the CEO and co-founder of Te?ted Oy as well as a co-inventor of TICKPLEX and TOXIPLEX

I have no other statement of disclosures

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Misconception: Inaccuracy of Lyme Disease Tests

Truth:
Lyme Disease Tests Are Accurate

Image by Klaus Nielsen

Learning Objectives

The goal:

to demonstrate how international ISO standards and NICE guidelines work together to improve diagnostic accuracy.

Importance of the Topic:

Public health implications

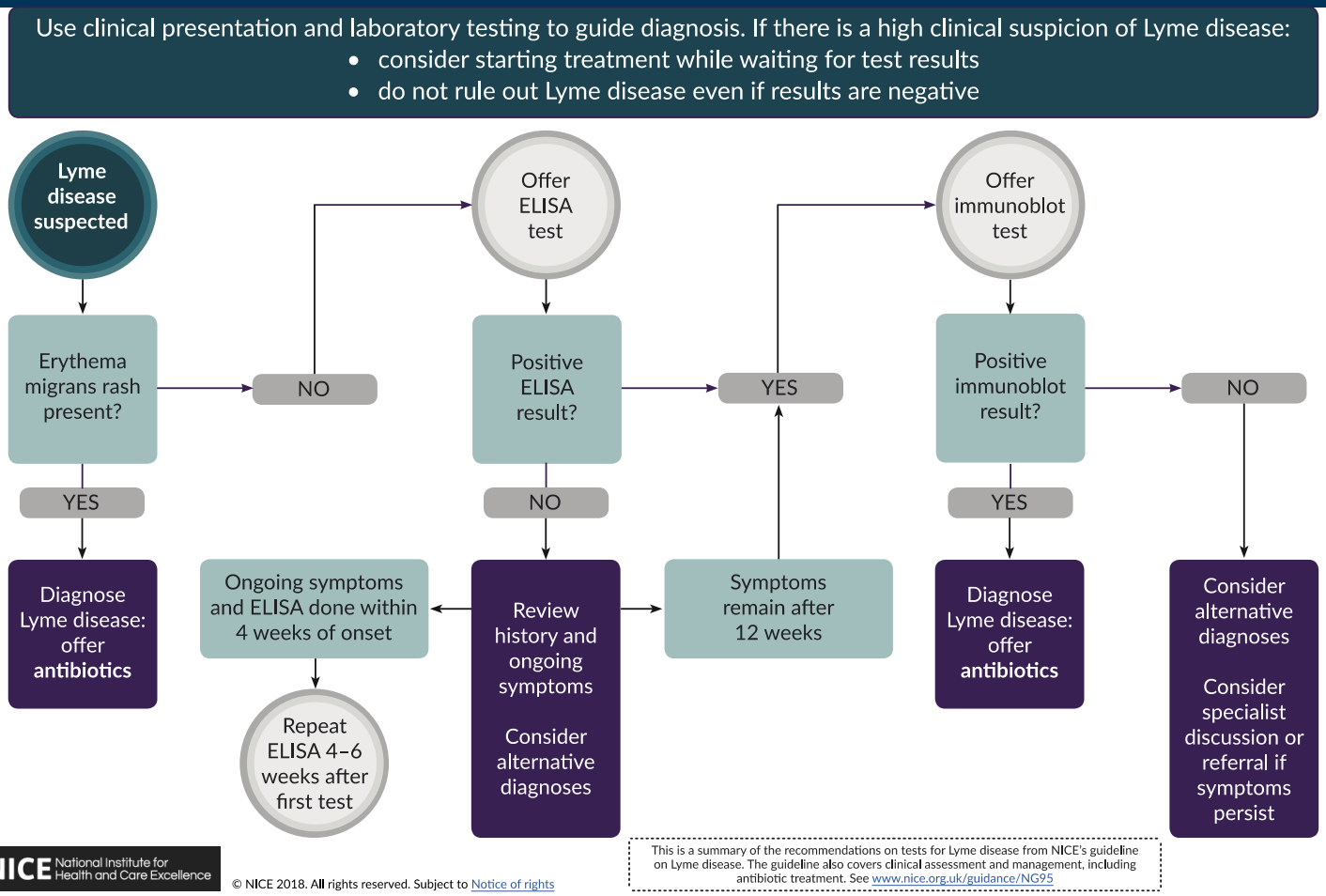
Human rights aspects (timely diagnosis and treatment)

Misconception: Inaccuracy of Lyme Disease Tests

Myth:
Lyme Disease Tests Are Notoriously Inaccurate

Image by Klaus Nielsen

Guidelines of Diagnosing Lyme Disease



https://www.nice.org.uk/guidance/ng95/chapter/Recommendations#laboratory-investigations-to-support-diagnosis

Test for both IgM and IgG antibodies using ELISAs based on purified or recombinant antigens derived from the VlsE protein or its IR6 domain peptide (such as C6 ELISA).

No demand of certain antigens on immunoblot.

The NICE Guidelines for Lyme Disease Diagnosis

Testing Strategy:

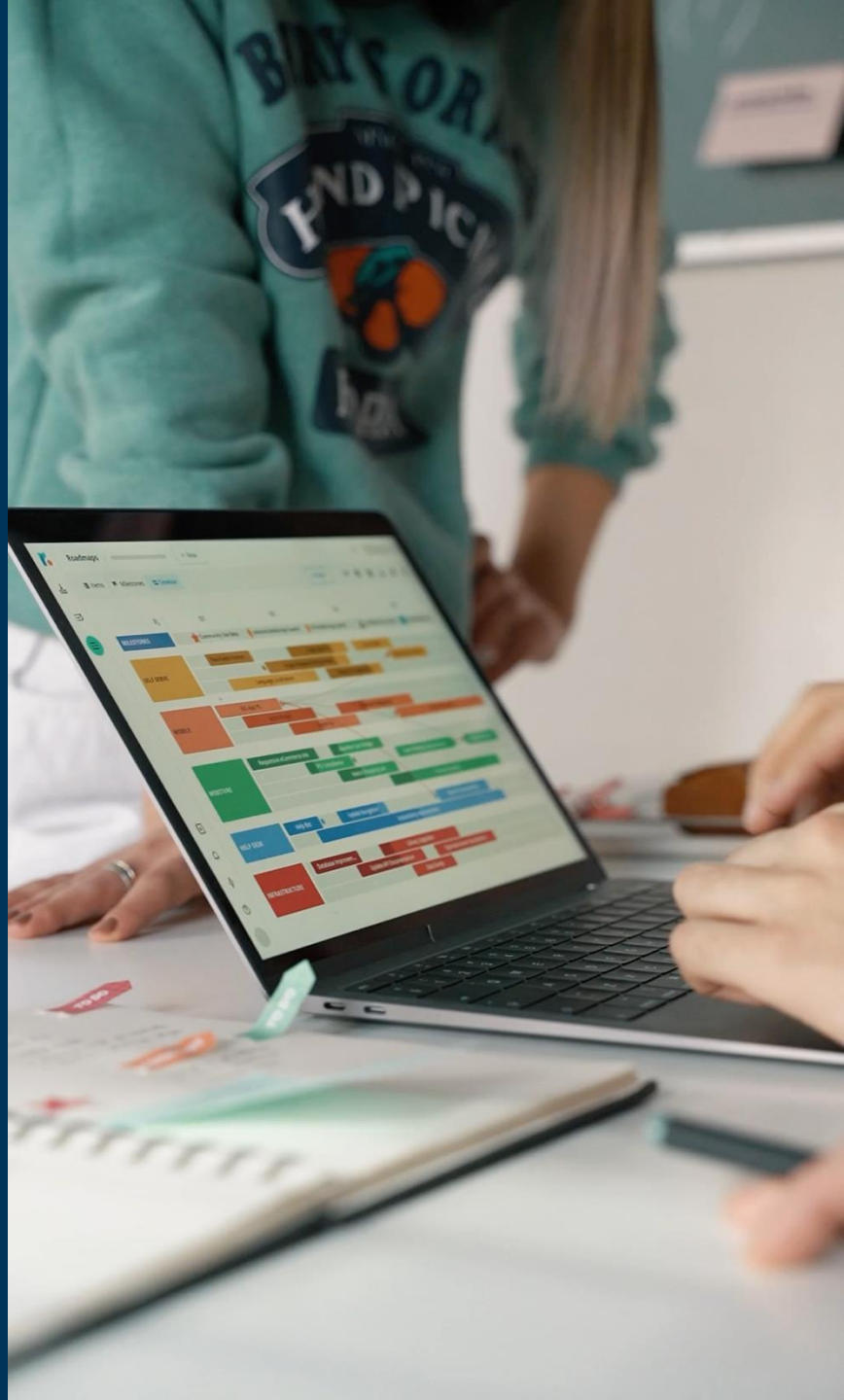
- **2-Tier Testing System:** ELISA (IgM & IgG) followed by confirmatory Immunoblot.
- Use of combined IgM/IgG ELISA based on VlsE protein or C6 for better sensitivity and specificity.

Key Diagnostic Recommendations:

- Diagnosing without laboratory tests for erythema migrans cases.
- Importance of clinical judgment alongside lab results.

Handling Negative Results:

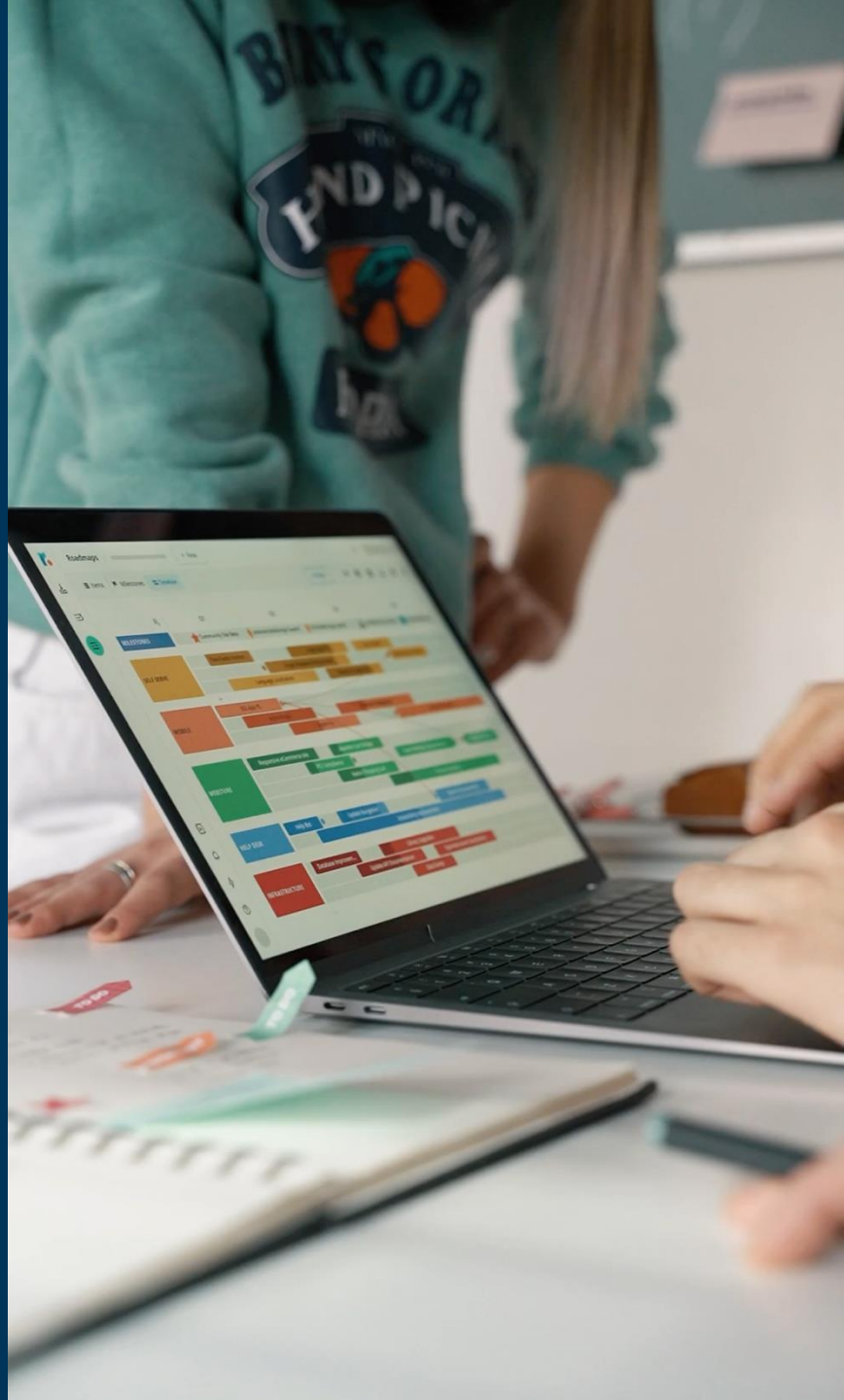
- Re-testing protocols and referral pathways.



The NICE Guidelines for Lyme Disease Diagnosis

Carry out tests for Lyme disease only at laboratories that:

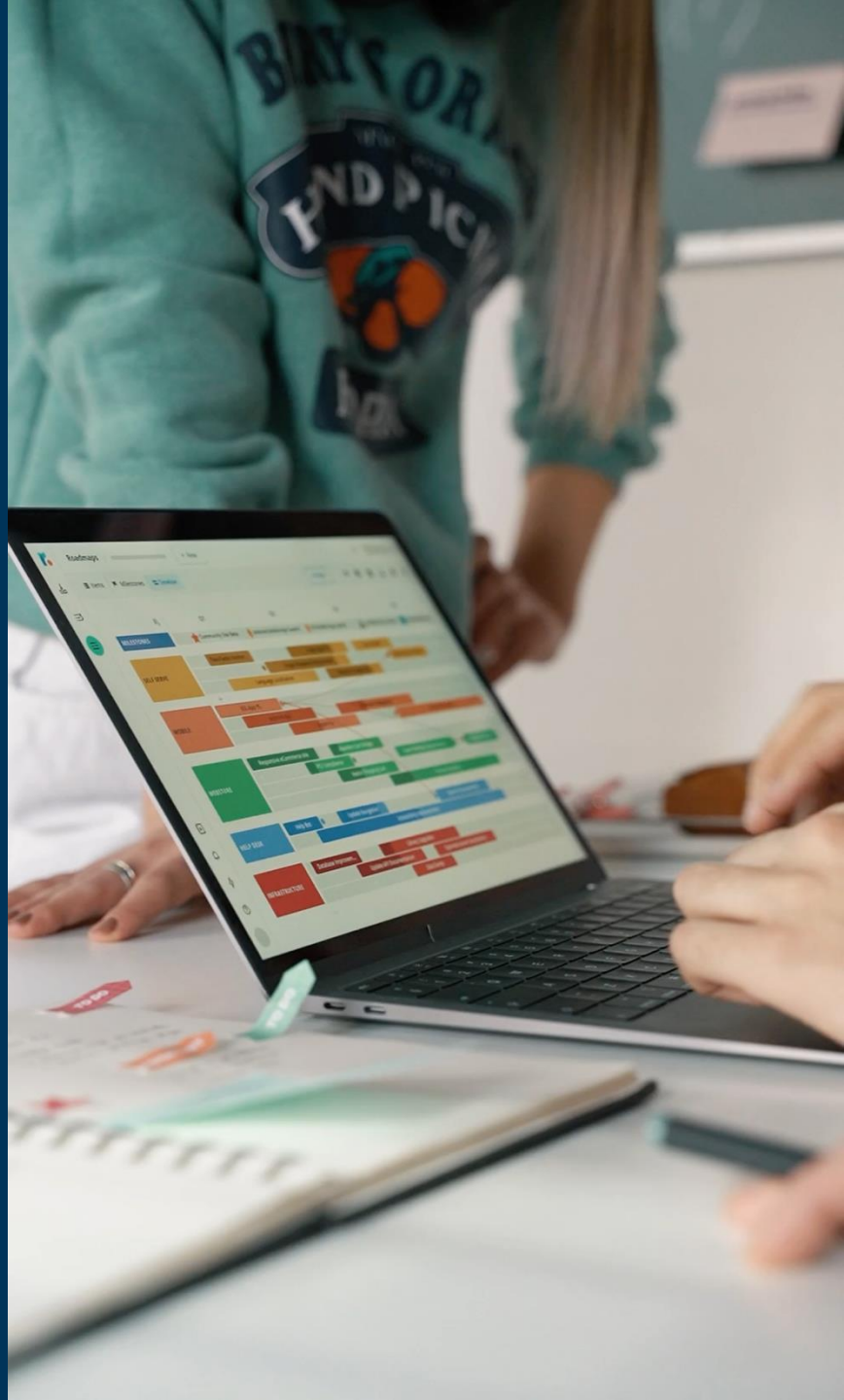
- are accredited by the UK accreditation service (UKAS)
- use validated tests (validation should include published evidence on the test methodology, its relation to Lyme disease and independent reports of performance)



The NICE Guidelines for Lyme Disease Diagnosis

Carry out tests for Lyme disease only at laboratories that:

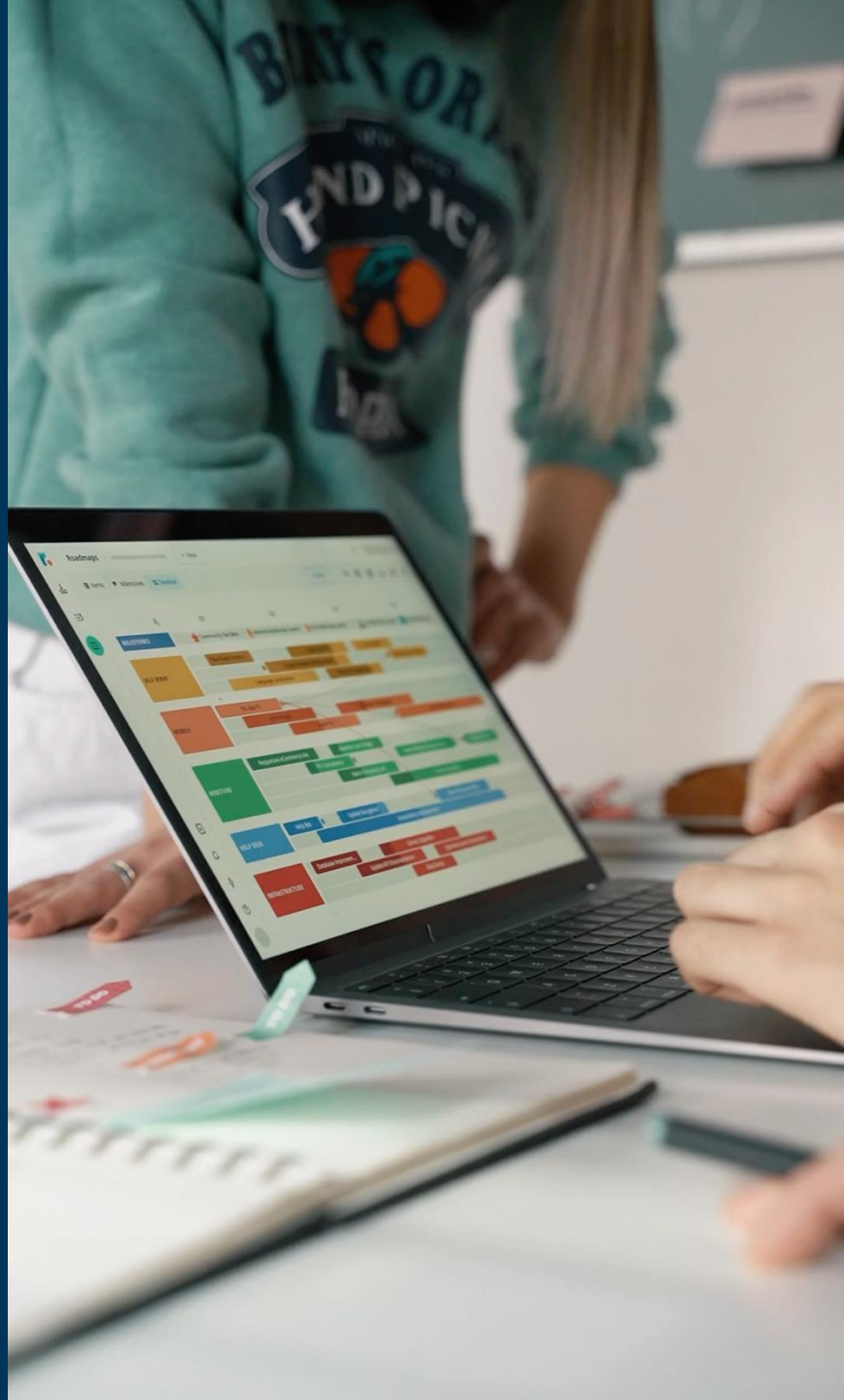
- participate in a formal external quality assurance programme.



The NICE Guidelines for Lyme Disease Diagnosis

Do not routinely diagnose Lyme disease based only on tests **done outside the NHS**, **unless** the laboratory used is **accredited**, participates in formal external quality assurance programmes and uses **validated tests**

https://www.nice.org.uk/guidance/ng95/chapter/Recommendations#laboratory-investigations-to-support-diagnosis



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Misconception: Inaccuracy of Lyme Disease Tests

Myth: Lyme Disease Tests Are Notoriously Inaccurate

ISO 13485:2016 outlines the criteria for a quality management system (QMS) designed specifically for the medical devices sector.
Demands of analytical and clinical validation.

National Medical Device Agencies like FDA, IVDR, FIMEA demand analytical and clinical validation and some of the agencies demand QMS.

Misconception: Inaccuracy of Lyme Disease Tests

Myth: Lyme Disease Tests Are Notoriously Inaccurate

ISO 15189 establishes the criteria for excellence and proficiency in medical laboratories, guaranteeing the accuracy and reliability of test findings.

***Accreditation agencies, such as the College of American Pathologists (CAP) and the United Kingdom Accreditation Service (UKAS), provide certification to laboratories based on ISO 15189.**

***Demands of independent analytical and clinical validating of all medical devices such as IVDs.**

Misconception: Inaccuracy of Lyme Disease Tests

Truth:
Lyme Disease Tests Are Accurate

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Guidelines of Diagnosing Lyme Disease

Carry out tests for Lyme disease only at laboratories that:

- **are accredited by the UK accreditation service (UKAS) and**
  - ISO15189 is equivalent and UKAS will provide letter to attest
  - www.ukas.com/accreditation/standards/medical-laboratory-accreditation/

"We can also provide labs that are accredited by another national authority with a formal letter confirming this."

- **use validated tests (validation should include published evidence on the test methodology, its relation to Lyme disease and independent reports of performance) and**
  - CE and IVD marked follows IVDR (ISO13485 equivalent) so equivalent to Medical devices, and In Vitro Diagnostics (IVDs), regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).
  - www.gov.uk/government/publications/in-vitro-diagnostic-medical-devices-guidance-on-legislation

- **participate in a formal external quality assurance programme.**
  - Demanded in ISO15189
  - www.iso.org/standard/56115.html

Misconception 10: Trust in Foreign Laboratories

***116 accreditation bodies that comply with ISO 15189:** International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (ILAC MRA).

***UKAS, FINAS, DAkkS, NATA, etc provide certification to laboratories based on ISO 15189 and are apart of ILAC.**

***As a result of UKAS's involvement in the ILAC MRA, the NICE recommendations for Lyme Disease Diagnosis officially support all laboratories that comply with ILAC standards.**

Truth: You Can Trust Foreign Laboratory Results

ILAC MRA facilitates global collaboration, guaranteeing that laboratories that adhere to stringent criteria deliver reliable and uniform diagnostic findings, thereby enhancing patient care and clinical outcomes.

Case Study: ArminLabs

Carry out tests for Lyme disease only at laboratories that:

- **are accredited by the UK accreditation service (UKAS) and**
  - ISO15189 is equivalent and UKAS will provide letter to attest

DakkSs accredited, Signatory to ILAC, also CAP-accredited (USA) that is ISO15189 equivalent and CLIA accredited (USA) and used CE and IVD marked diagnostic kits

- **use validated tests (validation should include published evidence on the test methodology, its relation to Lyme disease and independent reports of performance) and**
  - CE and IVD marked diagnostic kits that follow national and EU regulation for selling must have QMS (ISO13485 equivalent) as mandated by Medicines and Healthcare products Regulatory Agency (MHRA).
  - RUO does not qualify with this mandate

- **participate in a formal external quality assurance programme.**
  - Demanded in ISO15189, CAP demanded

Why Accept Foreign Laboratory Tests?

International Trust and Recognition: Tests validated under ISO 13485:2016 and conducted in ISO 15189-accredited labs are **globally recognized for their reliability.**

Consistency in Diagnostic Quality: The ILAC Mutual Recognition Arrangement (ILAC MRA) facilitates **global equivalence** of accredited laboratories, ensuring diagnostic results are consistent across borders, thus reducing the need for redundant testing when patients seek care across different healthcare systems.

Improved Patient Outcomes: Timely and accurate diagnoses enabled by recognized foreign tests can lead to **better patient care and disease management**.

Regulatory Efficiency: Acceptance of internationally validated tests reduces redundancy, **minimizes delays in diagnosis**, and aligns with global best practices, ultimately streamlining healthcare delivery in global patients.

Why Accept Foreign Laboratory Tests?

Acceptance strengthens countries' healthcare systems by **reducing diagnostic gaps**, promoting **international collaboration,** and **fostering innovation** in diagnostic technologies.

Human Rights Implications

Denying recognition of validated foreign tests can **lead to delayed diagnoses** and treatment, potentially infringing on the right to health.

Recognizing these tests **ensures equitable access** to high-quality diagnostics, regardless of geographical origin, aligning with the **country's commitment to upholding human rights and health equity**.

No laboratory or clinician should question the validity of Lyme disease diagnostics if the laboratory adheres to ISO 15189 and the IVD is manufactured under ISO 13485:2016 standards.

Questions and Answers

Let's change the narrative!

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