



Quality Assurance Guidance

for the

**Procurement of COVID-19 Point of Care, Near Point
of Care and Laboratory Diagnostic Technologies**

UNICEF Supply Division

Quality Assurance Centre

Version 1.0, 17th March 2020

Revisions

Version	Date of Issue	Description
Draft	Mar 2020	Initial draft for comment
Draft 2.0	Mar 2020	Comments received and addressed
Version 1.0	17 th March 2020	Approved for use by QAC and HTC

1. Introduction

Regulatory systems for In Vitro Diagnostics (IVD) are primarily intended to help protect and promote the public health and safety. Public trust and confidence in these systems depends upon the maintenance of quality, safety and performance of IVD technology throughout their lifecycle.

2. Scope

This Quality Assurance (QA) guidance sets out the QA requirements in relation to only the selection and procurement of the COVID-19 Point of Care (PoC), Near PoC and Laboratory Diagnostic Technology by UNICEF Supply Division.

3. QA Guidance

For the procurement COVID-19 Point of Care (PoC), Near PoC (near-PoC) and Laboratory Diagnostic Technologies the following standards and requirements shall be met as a minimum.

1. All products shall be manufactured at a site compliant with the requirements of ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes¹ that has been audited and certified by a Notified Body that is accredited by the Competent Authority of one of the Management Committee Members of the IMDRF²

In addition to the requirements for the Quality Management System the following shall also apply;

2. Any COVID-19 PoC, Near-PoC and Laboratory Diagnostic Technology shall be WHO Prequalified and listed on the WHO website as such, or,
3. The COVID-19 PoC, Near-PoC and Laboratory Diagnostic Technology shall have undergone:
Either
 - a. A WHO Emergency Use Evaluation and Listing of IVD's (EUAL)**Or**
 - b. Undergone a US FDA Emergency Use of Medical Products and Related Authorities (EUA), or,
4. The technology has been authorised for use by a Conformity Assessment Body that has been designated by one of the IMDRF Members³ Competent Authorities⁴, or,
5. A recommendation to procure based on the advice of a qualified Expert Review Panel, or,
6. A recommendation as a result of an independent assessment conducted by UNICEF SD. This assessment will constitute as a minimum an independent lab test,

¹ <https://www.iso.org/standard/59752.html>

² <http://www.imdrf.org/about/about.asp#mcm>

³ <http://www.imdrf.org/about/about.asp#man>

⁴ <http://www.imdrf.org/consultations/cons-rrar-cabc-mdrr.asp>

conducted at a WHO approved facility. A dossier review and a manufacturing site inspection in relation to the application of the QMS.

Notes.

1. In the case of any Technology being submitted via the methods above and where no manufacturing site visit was carried out as part of the QMS review then a manufacturing site visit may be conducted by UNICEF SD or a nominated third party to evaluate the application of the manufacturing Quality Management System.
2. While there are travel restrictions in place as a result of the Covid-19 Pandemic, by Governments and/or UNICEF Supply Division, then a detailed desk review of the manufacturers documented QMS may be requested in lieu of a manufacturing site inspection. The requirements for this will be communicated separately if required.
3. Any technology being self-assessed under the CE Class I route shall have clinical data studies included in any bid submission.
4. Any technology submitted with CE marking is to further demonstrate that all the current and relevant requirements under the new MDD/IVDD have been taken into account and that the relevant legislation has been followed in relation to engaging appropriate Notified Bodies⁵

⁵ <https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main>