WHO Prequalification of In Vitro Diagnostics Update

Issue 29
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1. PREQUALIFIED IVDs

We are very pleased to announce the prequalification of the following products:

Product name	Product code(s)	Manufacturer	Date of Prequalification
Alinity m HCV	08N50-090; 08N50-080; 08N50-070	Abbott Molecular Inc	6 March 2020
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20D	SD Biosensor, Inc.	6 March 2020
STANDARD Q Malaria P.f Pan Ag Test	09MAL30D	SD Biosensor, Inc.	6 March 2020
STANDARD Q Malaria P.f Ag Test	09MAL10D	SD Biosensor, Inc.	6 March 2020
STANDARD Q HCV Ab Test	09HCV10D	SD Biosensor, Inc.	5 March 2020
Monolisa HCV Ag-Ab ULTRA V2	72561 and 72562	Bio-Rad	24 January 2020

For a complete list of prequalified products, click here.

For a list of products undergoing prequalification assessment, visit this page.

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2. COVID-19 PANDEMIC AND EMERGENCY USE LISTING

On 30 January 2020, the Director-General declared that the outbreak of SARS-CoV-2 constitutes a Public Health Emergency of International Concern (PHEIC). As a consequence, the WHO Prequalification Team announced that the Emergency Use Listing (EUL) is open to candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. An invitation to manufacturers of IVDs to detect SARS-CoV-2 to submit an Expression of Interest (EOI) for assessment of candidate IVDs under the EUL procedure was issued on 28 February 2020.

The EUL procedure is developed to expedite the availability of IVDs needed in public health emergency situations. It is intended to assist interested procurement agencies and Member States on the suitability for use of a specific IVD, based on a minimum set of available quality, safety, and performance data.

Manufacturers who are interested in an EUL submission for assays to detect SARS-CoV-2 are invited to contact diagnostics@who.int to arrange a pre-submission meeting/call. Please note that applications won't be accepted without prior consultation with WHO.

Currently, assays for the detection of SARS-CoV-2 nucleic acid are eligible for EUL submission. Instructions for manufacturers detailing the technical specifications for the documentary evidence can be found here.

Weekly updates outlining the status of EUL applications can be found here.

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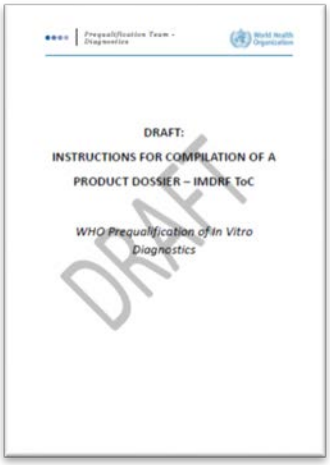
3. TRANSITION TO THE INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) TABLE OF CONTENTS (ToC) FORMAT FOR PRODUCT DOSSIER SUBMISSIONS



In March 2020, the WHO Prequalification of In Vitro Diagnostics began to transition to the International Medical Device Regulators Forum (IMDRF) Table of Contents (ToC) format for product dossier submissions. WHO PQ will move away from product dossiers that use the Global Harmonization Task Force (GHTF) Summary Technical Documentation (STeD) format.

The ToC format seeks to harmonize both layout and content of documented evidence provided in support of regulatory (and for WHO purposes, prequalification) submissions. Implementation of the ToC dossier format will allow alignment with international best practice as uptake of the new format proceeds. It will also allow for dossier reviews that will be compatible for use in those countries participating in WHO's Collaborative Registration Procedure.
Over the following 12 months WHO PQ will accept product dossiers in either the current STeD format, or the new ToC format. In 2021 dossiers will be accepted in the ToC format only. Manufacturers prepared to use the new ToC format should compile and submit the product dossier as prescribed by the new WHO document "PQDx_018 v4 Draft: Instructions for Compilation of a Product Dossier – IMDRF ToC".

This draft document is open for **public comment until March 2021**. Any comments may be directed to diagnostics@who.int

Manufacturers may still submit their product dossier according to the current STeD format until April 2021.

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4. INTERNATIONAL COLLABORATION AND HARMONIZATION

The WHO Prequalification Unit actively participates in several regional and international collaboration and harmonization initiatives of relevance to prequalification assessments, including the International Medical Device Regulators Forum (IMDRF) and the Asian Harmonization Working Party (AHWP). Both the IMDRF and AHWP develop guidance documents which assist countries in regulatory harmonization and convergence. Guidance development includes a public consultation phase. Documents undergoing public consultation can be accessed through the IMDRF and AHWP websites.

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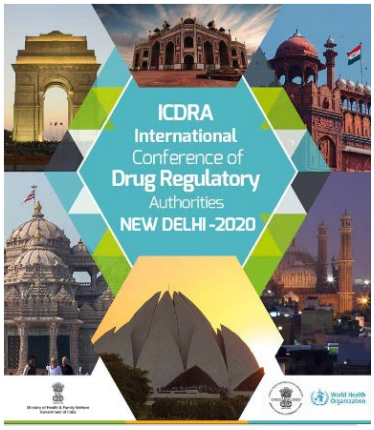
5. UPCOMING EVENT: 19th ICDRA SCHEDULED 28 SEPTEMBER - 02 OCTOBER 2020



The International Conference of Drug Regulatory Authorities (ICDRA) provide drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. Regulatory authorities are continually faced with new issues - such as globalization and extension of free trade - while increased responsibilities from expansion of the market and the improvement and sophistication of products place heavy demands on regulatory systems and knowledge bases. The development of cutting edge technologies and health care techniques and extensive use of the Internet impose further complex challenges. ICDRA has been instrumental in guiding regulatory authorities, WHO and interested stakeholders in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines and herbals. The conferences have been convened since 1980 with the aim of promoting exchange of information and collaborative approaches to issues of common concern. As a platform established to develop international consensus, ICDRA continues to be an important tool for WHO and drug regulatory authorities in their efforts to harmonize regulation and improve the safety, efficacy and quality of medicines.

The Central Drugs Standard Control Organization (CDSCO) of India will host of the next 19th International Conference of Drug Regulatory Authorities (ICDRA) from 28 September to 2 October in New Delhi, India. The conference will focus on Smart Regulation: Delivering Quality Assured Medical Products for All and will include two sessions on medical devices. Registration is open for both pre-ICDRA and ICDRA.

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