Health Technology Review	
Technology Ref.:	HTA24014
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Technology Name/Version/Model:	Multiplex Real time PCR Kit for Twenty-three Respiratory Pathogens (Ready-to-Use)
Approvals by International Bodies (year):	MoHaP and CE Marked
Manufacturer/ Company name, country of Origin	UniMedica, China
Agent in UAE:	Instamed Medical Equipment Trading LLC
Class/ Type	NA
Licensed Indications	Multiplex Real Time- PCR for the detection of 23 respiratory Pathogens in a single test.
Cost and Comparisons with standard of Care	Estimated 80-90 AED CPT.
Administration/ Use	It's a multiplexing PCR detection kit in which only need to run a single sample for the simultaneous detection of 23 respiratory pathogens including Bacteria and Viruses. Results usually comes in few hours

Short Description of the Technology:	• Introduction. A pathogen is a virus, bacteria, or other organism that causes an illness in the respiratory tract. A respiratory pathogens (RP) panel checks the timely detection of pathogens of the respiratory tract such as to diagnose flu, common cold, RSV cause usually mild respiratory infection. But it can be dangerous to babies and the elderly, Adenovirus cause different type of Infections such as pneumonia and croup Covid -19 and Bacterial infections, etc. • Mechanism of Action. 1. The principle of the kit is based on simply" Taqman Probe Multiplex Real Time PCR". 2. Multiple Primers & probes are used to detect 23 individual pathogens from the samples. 3. such as Oropharyngeal swab, Sputum, BAL & Nasopharyngeal swab. 4. Extraction can be done from any available Extraction system in the lab, similarly after. 5. extraction PCR can be validated on the any available PCR machine in the Lab. 6. Test results are based on the CT- values.

	7. Quality checks are done with the available Positive Control (PC), Negative Control (NC), and endogenous internal Control (IC). • **Clinical Evidence/ Efficacy.** According to the "Registration technology of multiple nucleic acid detection reagent for respiratory virus Review Guidelines", the clinical trial should select similar products that have been listed as the comparison product. the "ePlex® Respiratory Pathogen Panel 2" produced by GenMark Diagnostics, Inc. is used as the comparison reagents. In this clinical trial, 972 cases were collected in the institution,36 RSV positive samples, 34 hRV positive samples,33 NL63 positive samples,32 HKU1 positive samples, 29 229E positive samples, 28 OC43 positive samples,36 MERS positive samples,43 LP positive samples, 31 PIV1 positive samples, 37 PIV2 positive samples,42 AdV positive samples,43 PIV3 positive samples, 47 hBoV positive samples, 38 hMPV positive samples,39 MP positive samples, 31 CP positive samples, 29 FluA positive samples,37 FluB positive samples,38 FluA-H1 positive samples, 41 SARS-CoV positive samples, 44 FluA-H3 positive samples,40 hEV positive samples,33 SARS-CoV-2, positive samples,and 131 Compared of test reagent and comparison reagent results, the clinical sensitivity was 99.6%, clinical specificity was 99.2%, total coincidence rate was 99.6%. The results showed that the Multiplex Real time PCR Kit for Twenty-three Respiratory Pathogens Ready-to-Use) developed by Shenzhen Uni-medica Technology Co., Ltd. is highly consistent with the comparison reagent and clinical diagnostic / exclusion results, which can meet the needs of clinical detection, and • Safety/ Risk issues. There is No risk for the patients and Healthcare practitioner. The test should be performed by the trained technologist. • Place in therapy/ diagnosis. Can be used for suspected respiratory syncytial virus (RSV), human rhinovirus (hRV), coronavirus (NL63, HKU1, 229E, OC43, MERS), Legionella pneumophila (LP), parainfluenza virus 1 (PIV1), parainfluenza virus 2 (PIV2), parainfluenza virus 3 (PIV3), adenovirus (AdV), Humanbocavirus (hBoV), human metapneumovirus (hMPV), Mycoplasma pneumoniae (MP), Chlamydia pneumoniae (CP), influenza A, influenza B, Influenza A virus H1 , Influenza A virus H3, SARS-CoV, SARS-CoV-2 , Enterovirus (hEV) infection cases, suspected cases due to clustering and other diagnostic or differential diagnostic samples.

Health Technology Assessment Team Recommendation:	Approved

Summary of Review:

- Multiplex real-time PCR kits enable the detection and quantification of multiple target DNA or RNA sequences in a single reaction, increasing efficiency and reducing reagent use.
- The clinical sensitivity was 99.6%, clinical specificity was 99.2%, total coincidence rate was 99.6%.

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

1. Multiplex Real time PCR Kit for Twenty-three Respiratory Pathogens (Ready-to-Use).
2. Perform the test in local laboratories equipped with specialized equipment and expertise.
3. Ensure that Standard Operating Procedures (SOPs) are maintained for sample collection, processing, and analysis.
4. Provide comprehensive training for laboratory personnel.
5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
6. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Multiplex Real time PCR Kit"

- **Population/ Intended User**;
  - Patients require rapid and accurate identification of respiratory pathogens.
- **To be performed by**:
  - Clinical Laboratory Technicians
- **Clinical Setting:**
  - Laboratories and hospitals.
- **Condition of use:**
  - As per manufactural instructions.
- **Exclusion criteria:**
  - Recent infections, especially those targeted by the PCR test, might impact results due to residual nucleic acids. Patients should provide a history of recent illnesses.
  - Conditions that affect the immune system (e.g., HIV/AIDS, autoimmune disorders) or chronic infections might influence test results. Patients should disclose their complete medical history, including chronic illnesses.
  - Immunocompromised patients might have altered pathogen loads or atypical presentations of infections, which could influence PCR results.