Health Technology Review	
Technology Ref.:	**HTA21008**
Technology Name:	**Pintar NextGen PCR**
Approvals by International Bodies:	**CE-Marked**
Company name:	**Luxor Trading Group**
Agent in UAE:	**-**
Email:	**zak@luxortrading.nl**

Short Description of the Technology:	The Pintar NextgenPCR device is a new technology used for COVID-19 testing that heats and cools the PCR samples instantly, losing no time getting the samples on the desired temperature. The device delivers high speed, accuracy and by that significantly increased throughput. It is capable of producing a PCR test result within 30 minutes.

Health Technology Assessment Team Recommendation:	**Approved with limitation**

Summary of Review:

The Pintar NextgenPCR is ultrafast RT-PCR has been validated locally by Union71.

Local Validation Result:

Validation result at Union71 cover around 96 samples shows 89.4% sensitivity and 98% specificity

Advantages	Disadvantages
Very Fast in producing the results (Less than 30 minutes)	Additional analysis step using florescence scanner is needed for the sensitivity of the results. Due to scanner optical limitations
Needs fewer steps to produce the results which means shorter protocols	Initial costs of the device could be high due to the nature of Quantitative PCR platforms along with the need for skilled personnel.
One Machine can produce up to 9216 tests every 12 hours	Declaration of conformity was only done for the product but no evidence provided for the reagents.
Excellent sensitivity (89.4%) and specificity (98%) as per the validation result at Union71.	Not to be used for asymptomatic cases
Require less consumables	Confirmation by RT-PCR is required
Open system that can use reagents and consumables from other suppliers	

We recommend an **approval of using this technology** only with the following conditions:

1. Using the technology as a point of care testing for symptomatic cases only and positive cases to be confirmed with the gold standard RT-PCR.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

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