



Health Technology Review	
Technology Ref.:	HTA23028
Technology Name:	Chemistry Analyzer EXC200
Approvals by International Bodies:	CEIVD mark
Company name:	Al Bahar Al Azraq Drug Store
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Short Description of the Technology:	The Chemistry Analyzer is an automated device for in vitro diagnostic use in clinical laboratories. It is used for the quantitative detection of chemical components in serum, plasma, urine and other samples.
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The technology is a medical device used in clinical laboratories to analyze biological samples such as blood, serum or plasma. The analyzer is designed to measure variety of chemical substances such as enzymes, electrolytes hormones, lipids and proteins. Its uses photometric method to measure the color intensity of a sample to determine the concentration of specific analyte. The analyzer is acritical tool in diagnosing and monitoring different diseases such as heart disease, diabetes, and kidney function, it could be used in hospitals, clinics and labs, help physician in make accurate and fast decision and enhance treatments.</p>	
Advantages	Disadvantages
High throughput; Constant 400 T/H; processing many samples quickly, making it useful in high volume testing situations.	To be used by healthcare professional only
Results can be printed automatically when sample test finishes	The device requires regular calibration & maintenance to ensure measurement accuracy and this maybe a time consuming & expensive
The device analyses wide range of tests	The device is complex and require special training to operate
Advance technology; photometric method which enhance the accuracy and quality of the results	
The device is CE marked	
Automated device & results; can create automated reports for the results and transmit it to the patient electronic record.	
We recommend an <b>approval of using this technology</b> with the following conditions:	

1. The approval on using Chemistry Analyzer version EXC200.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. 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 “Chemistry Analyzer EXC200”

- **Population/ Intended User;**
  - to analyze biological samples such as blood, serum or plasma.
- **To be performed by:**
  - By medical lab technician/technologist.
- **Clinical Setting:**
  - Hospitals, clinics, laboratories.
- **Condition of use:**
  - As per manufacture instruction.
- **Exclusion criteria:**
  - Other conflicting medical issues.