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INSTRUMENT STANDARD OPERATING PROCEDURE MANUAL

College of Medicine

SAFETY AND LABORATORY COOMMITTEE, C.O.M, K.F.U.

Prepared by

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Document History

Document Section	Details of Amendments	Date	Modified by (Initials)
SOP	First Draft on SOP for the operation of **Vidas to measure hormones**		

1. OBJECTIVE

- The document describes the operation **Vidas to measure hormones**

2. SCOPE

VIDAS is a compact automated multiparametric immunoanalyzer including:

- The VIDAS analytical module divided into five independent sections each containing six assays with compatible protocols,
- The VIDAS PC software allowing up to two VIDAS modules to be operated,
- The reagents presented in kits of 60, 30 or 10 unit tests including the SPR®s and reagent strips.
- The additional consumables required standard, control(s), solvent.
- The factory calibration data provided in the form of a bar code (MLE card).
- The package insert.

The basic VIDAS workflow steps consist of:

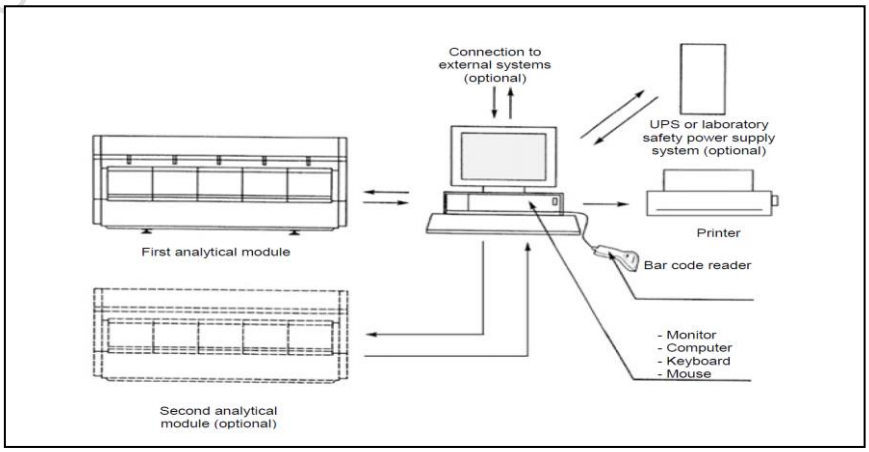
- Creating predefined sections.
- Performing calibrations and controls.
- Running assays.

VIDAS offers routine batch or random access (mixed) testing for:

- Serology
- Immunochemistry
- Antigen detection
- Industrial microbiology
- Immunohemostasis

The combination of two original concepts, sectioned architecture and single-dose reagents (SPR/Reagent Strip), offers:

- Reliable results.
- Ease-of-use.
- Rapid analysis results.



3. RESPONSIBILITIES

- ☐ It is the responsibility of designated personnel in the lab to train staff and students on this procedure and to ensure adherence to this procedure under supervision.
- ☐ It is the responsibility of designated personnel (staff or Student) to follow the instructions of this procedure under supervision.

4. REFERENCES

Vidas Instrument user's Manual.

5. DEFINITIONS

The SPR is a plastic (polypropylene or polystyrene) device capable of capturing soluble proteins, viruses and bacteria.

It is sealed with a color-coded dot and perforated in the center. Each SPR® is disposable.

6. SAFETY PRECAUTIONS

The power switch is located on the back of the analytical module. It must be easy to reach at all time.

7. PROCEDURE FOR OPERATING Vidas to measure hormones

7.1. Turning on the instrument:

Step 1 • Switch on the UPS, if required
Step 2 • Switch on the analytical module and leave it to warm up for 45 minutes.

Step 3 • Switch on the printer and screen.
Step 4 • Switch on the computer.
Refer to the section entitled "Starting VIDAS PC" in Chapter 3 of the VIDAS PC User's Manual.
Step 5 • Turn the power switch on the analytical module to the "OFF" position.
Step 6 • Wait for 1 minute and turn the power switch to the "ON" position.

7.2. Software Operation

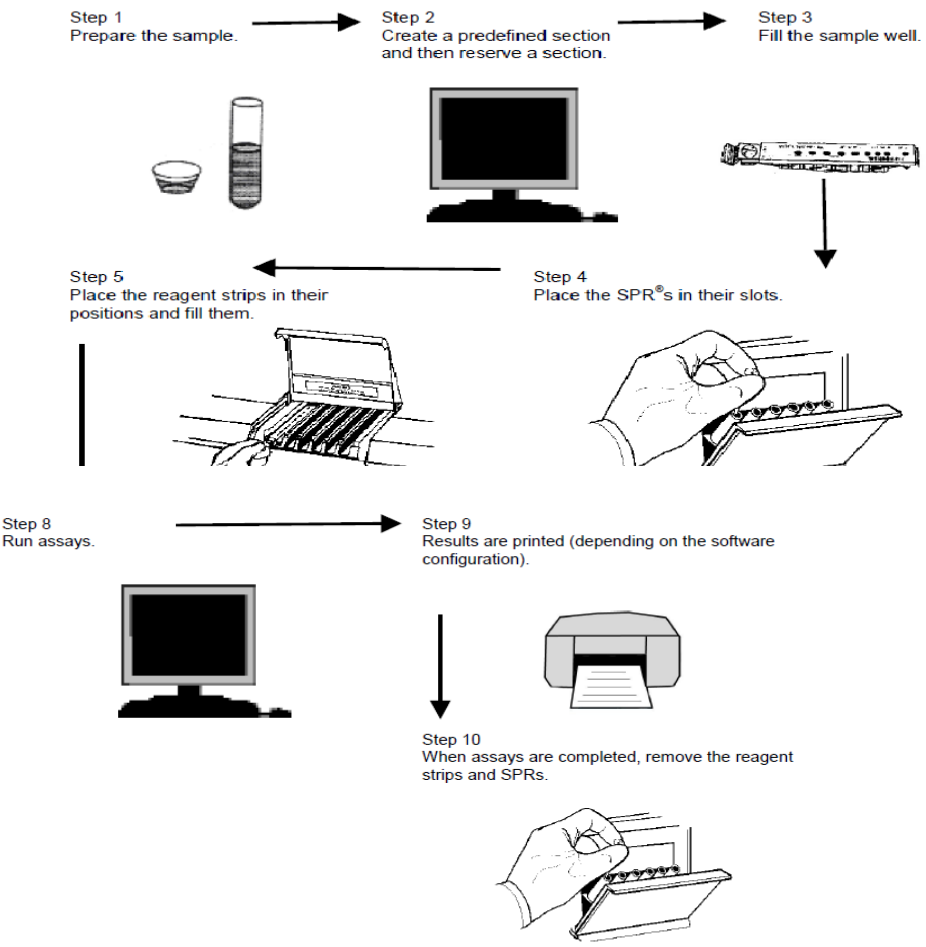
The software is multi-task and provides for:

− Entry of patient data and assays,
− Storage of calibrations in memory,
− Display and validation of results,

− System operation and self-tests,
− Management of patient records,
− Management of the uni- or bidirectional interface (optional).

7.3. *Steps of the Procedure*

Basic *VIDAS* work flow



Step 1. Prepare samples as described in the appropriate assay package insert.

Step 2. Create a predefined section, reserve a section and generate a loading report (see VIDAS PC User's Manual).

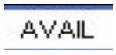
Step 3. To fill a reagent strip,
Place the prepared samples, standards and controls in the appropriate wells on the reagent strip.
The sample is placed in the sample well as indicated shown in the package insert.
The assay package insert specifies the volume of sample required to ensure proper performance of the assay.

Step 4. To load a SPR

- Open the SPR block door
- Place the SPR in the SPR block position directly above the corresponding reagent strip.

Step 5. To load a reagent strip

- Lift the cover of the reagent strip section.
- Holding it by its handle, insert a reagent strip into its assigned test position.
- Slide the strip into the position until it seats fully in the channel. The strip should now be firmly fixed in the channel.

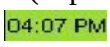
STEP 6. Close the SPR® block door(s).
STEP 7. Lower the cover(s) of the reagent strip section(s).
STEP 8. Run the assays.
STEP 9. Section status switches from 

to 

and then 

After having checked the reagent, VIDAS indicates the time of completion .

STEP 10 . When the assays are completed:

- A report is automatically printed (depending on the software configuration).
- Section status switches from 

(time of completion of the assay) to 

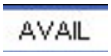
- The section door indicator light flashes to indicate that the reagent strips and SPRs should be removed.

STEP 11.

- Remove the completed reagent strips from each section used.
- Remove the used SPRs, making sure that each carries a color-coded dot.

When a SPR block door is closed after SPRs are removed,

- section status switches from 

to . 

- The section indicator light stops flashing, indicating that the section is free to Perform a new assay .

7.4. Turning off the Instrument

- Turn the power switch on the analytical module to the "OFF" position
- Switch oFF the computer
- Switch oFF the printer and screen
- Switch OFF the UPS, if required

7.5. Warning

All biological fluids should be considered as potentially infectious.
Protective gloves must be worn when manipulating blood, products derived from blood or objects contaminated with blood.
Qualified laboratory personnel should use acceptable procedures for biohazardous material.
