TECHNICAL BULLETIN: SQA-Vision and CLIA categorization

BACKGROUND

Interpretation and CLIA high complexity

The CLIA status of a test or of a device is determined according to an accumulated score divided into seven categories. Each category gives a score of 1-3, where A score of 1 indicates the lowest level of complexity, and a score of 3 indicates the highest level. The scores for the 7 criteria are added together and tests with a score of 12 or less are categorized as moderate complexity, while those with a score above 12 are categorized as high complexity.

One of the seven categories is "interpretation and judgement", which is defined as follows in the FDA's guidelines:

7 - Interpretation and judgment

- *Score 1. (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and (B) Resolution of problems requires limited independent interpretation and judgment.*
- *Score 3. (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and (B) Resolution of problems requires extensive interpretation and judgment.*

Note: a device can't be assigned with a moderate complexity CLIA status and have some of the features as high complexity.

Responsibilities between labs and manufacturers regarding CLIA status

In case of a CLIA moderately complexity or high complexity device, it is the responsibility of the lab/ facility using the device to make sure they have the required accreditation for using this device.

The responsibility for classification or re- classification of the CLIA status of a device is of the manufacturer.

OVERVIEW

SQA-V and SQA-Vision CLIA status

The SQA-V was assigned by a CLIA moderately complexed status, as part of its marketing clearance by the FDA.
The SQA-Vision was added to the SQA-V listing in an add- to – file process and the CLIA status was not changed.
The regulatory impact assessment that was done as part of the SQA-Vision product development, shows that various SQA-Vision features, such as morphology counter, Vitality and DNA fragmentation does not add complexity or require any Extensive independent interpretation. Therefor no change to the CLIA status is required:

Semen test	SQA-V	SQA-Vision	Regulatory Impact
MORPHOLOGY	• Manual morphology is assessed using the VISUALIZATION screen, a manual counter, and pad of paper with the abnormalities listed or through a microscope offline using a manual counter	• Manual morphology is assessed using the visualization screen, and an automatic counter. The counter marks the cell by color code, or there is the option to count without marking the cells. The counts are tabulated by the selected defects, and the defects are all determined and entered by the lab in the default set-up. • The test results are entered as	None- the analyses are the same, but Vision allows cataloging the results in an automatic and

Semen test	SQA-V	SQA-Vision	Regulatory Impact
	• The test results are entered into the test report manually in morphology abnormalities section of the report	MORPHOLOGY abnormalities / normal sperm cells on the VISION report automatically for the convenience of the user.	standardized manner.
VITALITY	• The sample is prepared per laboratory protocols • The sample is assessed manually through a microscope using a manual counter • The test results are entered into the test report manually in the 'other' category	• The sample is prepared per laboratory protocols • Select VITALITY from the list of VISION tests • The sample is assessed manually using the SQA-Vision visualization counter for Vitality for easy marking and capture of manual results. • The test results are automatically entered as manual VITALITY test results on the VISION report for the convenience of the user.	None- the analyses are the same, but Vision allows cataloging the results in an automatic and standardized manner.
DNA Fragmentation	• The sample is prepared per laboratory protocols • The sample is assessed manually through a microscope using a manual counter • The test results are entered into the test report manually in the 'other' category	• The sample is prepared per laboratory protocols • Select DNA Fragmentation from the list of VISION tests • The sample is assessed manually using the SQA-Vision visualization counter for DNA Fragmentation for easy marking and capture of manual results. • The test results are automatically entered as manual DNA Fragmentation test results on the VISION report for the convenience of the user.	None- the analyses are the same, but Vision allows cataloging the results in an automatic and standardized manner.

CONCLUSION

To conclude, since the morphology counter or any other feature of the SQA-Vision does not require "extensive independent interpretation and judgement", the SQA-Vision has no automatic assignment of the high complexity.

The SQA-Vision CLIA status remains the same as the SQA-V, moderate complexity.