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510(K) SUMMARY

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Trade Name: *MICRO21*TM with Retic
Classification Name: Automated Cell Locating Device
Classification Number: 81JOY
Class: II
Regulation Number: 864.5260

The *MICRO21*TM with WBC Diff (White Blood Cell Differential) Ref. No. K925670/A is an automated microscopic system that locates WBCs, stores digital images of the cells and displays the images in an organized manner to aid technologists in performing the WBC Diff procedure. The *MICRO21* process is substantially equivalent to the manual microscopic process.

Description:

The *MICRO21* with Retic is a new *MICRO21* intended use that follows the same process as the *MICRO21* with WBC Diff, but instead locates, digitally stores and displays reticulated red blood cells (retics) to aid the technologist in performing the Reticulocyte Count procedure. A retic is defined as a nonnucleated Red Blood Cell (RBC) that contains two or more blue-stained particles or granulo-filamentous material after staining with a supravital stain. A summary of the *MICRO21* with Retic process is as follows:

1. Prepare a blood wedge smear stained with a supravital stain.
2. Affix a bar code to each slide, place the slides into a frame holder, and insert the frame into the *MICRO21*.
3. The instrument locates 1000 RBCs.
4. The reticulated RBCs are stored as high magnification color images (1000x magnification).
5. The images of retics stored by the instrument are displayed on a color monitor for review by a technologist.
6. The technologist confirms that each reticulated RBC image displayed contains retic markings. If the image does not contain retic markings, the image is eliminated by the technologist and consequently not included in the retic count.
7. A report of the percent of retics per 1000 RBCs is printed.



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Test Methods:

Two testing methods were performed to validate the safety and effectiveness of the *MICRO21* with Retic process. To conduct the tests, two slides were created from forty patient samples, (80 slides in total) including normal and abnormal values.

Test Method One employed the NCCLS EP-9 requirements for qualifying a new methodology versus the manual methodology being replaced. Using forty specimens with two slides from each specimen for a total of 80 slides, two technologists independently performed a manual retic count on each of the 80 slides. The same 80 slides were run on the *MICRO21* with Retic with the two technologists reviewing the reticulated RBCs displayed by the *MICRO21*. The results of the 80 manual retic counts and the 80 *MICRO21* retic counts were analyzed against the NCCLS EP-9 Mean Correlation Standard. The *MICRO21* with Retic and the manual method showed a .95 mean correlation, which is within the NCCLS EP-9 requirements for a new methodology.

Test Method Two involved two certified technologists independently observing the *MICRO21*'s ability to locate RBCs and reticulated RBCs on 39 slides. Over 39,000 RBCs were located by the *MICRO21* with a sensitivity (agreement with the technologist) of 99.7%.

Conclusion:

The correlation determined by Test Method One, and the sensitivity determined by Test Method Two confirm the safety and effectiveness of the *MICRO21* with Retic for the intended use of location, storage and display of reticulated RBC's to aid the technologist in performing the Retic Count procedure.