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510(K) SUMMARY

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Trade Name: *MICRO21*TM with ANA
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 ANA is a new *MICRO21* intended use that follows the same process as the *MICRO21* with WBC Diff, but instead locates, digitally stores and displays ANA Images to aid the technologist in performing an ANA Screen for Positive or Negative results. An ANA Screen is a microscopic exam of a patient serum sample that has been set-up using an indirect enzyme antibody test for the semi-quantitative detection of antinuclear antibody (ANA) which is an aid in the detection of systemic rheumatic disease. The ANA Test System used on the *MICRO21* is Immuno Concepts® Colorzyme® ANA Test System. A summary of the *MICRO21* with ANA process is as follows:

1. Patient serum samples are prepared following the Colorzyme Test Procedure and then placed in designated wells on the ANA slide.
2. Each slide has three control wells and nine patient wells.
3. Barcode the slides, place the slides into a frame holder, and insert the slides on the *MICRO21* for processing.
4. The *MICRO21* locates the center of each well on the slide and captures four images from each well.
5. The ANA images are stored by the instrument and displayed on a color monitor for review by a technologist.
6. The technologist reviews the images and confirms that the *MICRO21*'s Positive/Negative determination is correct. If not correct, the technologist changes the determination.
7. A report of the ANA screening result for each patient well is printed.



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Test Method:

The Test Method compared 204 patient ANA images from the *MICRO21* to the same 204 patient ANA images viewed under a bright light microscope. This was done to confirm that the ANA image presentation on the *MICRO21* is equivalent to the ANA image presentation for the manual method under the bright light microscope.

The Test Method consisted of 204 patient ANA images with 112 Positives and 92 Negatives as identified by a technologist at Immuno Concepts® who manually read the 204 ANA patient tests using a bright light microscope. The ANA slides containing the 204 patient ANA tests were then loaded onto the *MICRO21* and an image from each sample was captured, stored, and displayed on the review monitor. A technologist reviewed each stored ANA patient image and graded the result as Positive or Negative. The results which are reported in the Summary of Results confirm that the ANA image presentation on the *MICRO21* is equivalent to the manual method.

Conclusion:

The image comparison performed in the Test Method confirms the safety and effectiveness of the *MICRO21* with ANA for the intended use of location, storage and display of ANA images to aid the technologist in performing the ANA Test Screen.