

510(K) SUMMARY

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Trade Name:	<i>MICRO21</i> TM with nDNA
Classification Name:	Automated Cell Locating Device
Classification Number:	81JOY
Class:	I 
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 nDNA is a new *MICRO21* intended use that follows the same process as the *MICRO21* with WBC Diff, but instead locates, digitally stores and displays nDNA Images to aid the technologist in performing a nDNA Screen for Positive or Negative results. A nDNA 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 nDNA which is an aid in the detection of systemic rheumatic disease. The nDNA Test System used on the *MICRO21* is Immuno Concepts® Colorzyme© nDNA Test System. A summary of the *MICRO21* with nDNA process is as follows:

1. Patient serum samples are prepared following the Colorzyme Test Procedure and then placed in designated wells on the nDNA 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 central area of each well on the slide and captures four images from each well.
5. The nDNA 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 a positive or negative determination by selecting the appropriate result.
7. A report of the nDNA screening result for each patient well is printed.



Intelligent Medical Imaging, Inc.

Test Method:

The Test Method compared 205 patient nDNA images from the *MICRO21* to the same 205 patient nDNA images viewed under a bright light microscope. This was done to confirm that the nDNA image presentation on the *MICRO21* is equivalent to the nDNA image presentation for the manual method under the bright light microscope.

The Test Method consisted of 205 patient nDNA images with 91 Positives and 114 Negatives as identified by a technologist at Immuno Concepts who manually read the 205 nDNA patient tests using a bright light microscope. The nDNA slides containing the 205 patient nDNA 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 nDNA patient image and graded the result as Positive or Negative. The results which are reported in the Summary of Results confirm that the nDNA 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 nDNA for the intended use of location, storage and display of nDNA images to aid the technologist in performing the nDNA Test Screen.

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