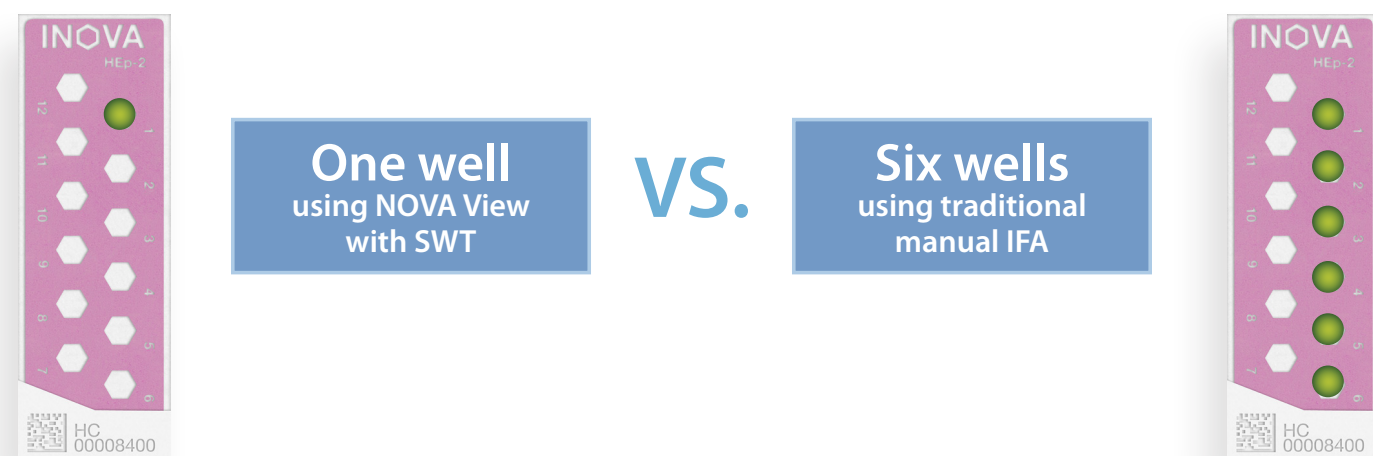


# Economic Benefits

## NOVA View single well titer reduces the overall number of HEp-2 wells used

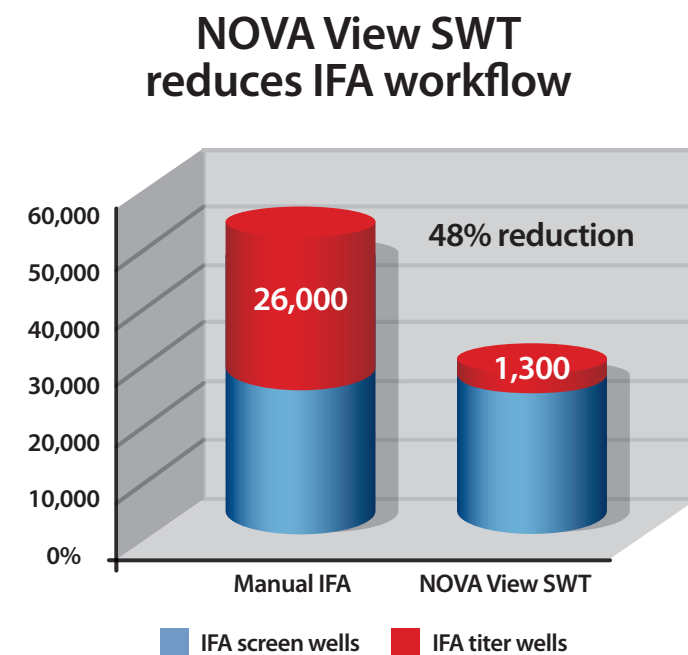
Example in a laboratory with an average volume of 100 ANA tests per day, a 20% positive rate, 5% of which are mixed patterns, performing 5 dilutions per well

- **ANA screen:** Both methods require the same number of wells for screening
- **Titer:** NOVA View SWT uses the light intensity from a single screening well to predict a titer, whereas manual IFA requires additional wells to provide a similar result



In this example, NOVA View has the potential to reduce the total number of IFA wells by 48%.

- NOVA View SWT reduces the number of dilution wells by approximately 24,700 each year in this example
- NOVA View SWT improves turnaround time, lowers material costs and reduces technologist hands-on time



# The Integrated Lab

## The Integrated Lab

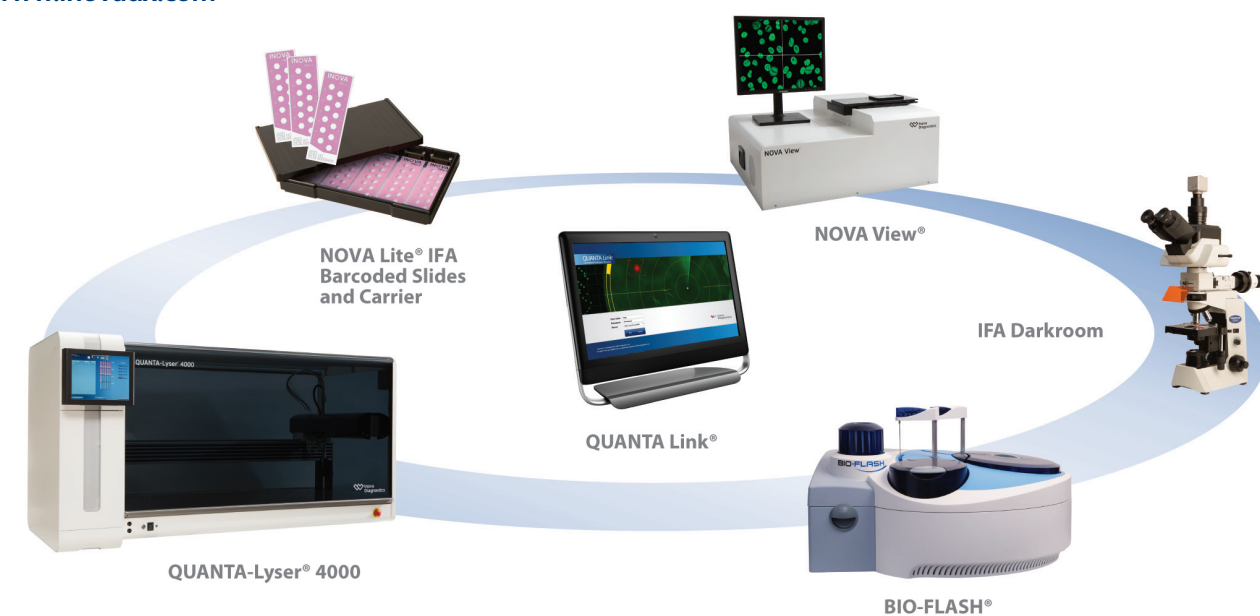
The Integrated Lab represents a new standard for improving workflow efficiencies in the autoimmunity laboratory. NOVA View is a key component in the Integrated Lab for automating IFA testing. Inova Diagnostic instruments are connected together by QUANTA Link®, a data management software program that exchanges data with the laboratory information system. The instruments and software that make up the Integrated Lab encompass:

- QUANTA-Lyser®, a fully automated EIA/IFA processor
- NOVA View®, an automated digital IFA microscope system
- BIO-FLASH®, a random access, continuous load chemiluminescent system

The Integrated Laboratory provides particular benefits for IFA testing:

- Significant reduction in hands-on time and improved workflow efficiencies
- Full traceability of patient samples from processing through reporting
- A paperless, transcription free laboratory operating environment
- Single point location for QC data including Levy Jennings trending
- Centralized data management system

For more information, please contact your local Inova Diagnostics sales representative or visit [www.inovadx.com](http://www.inovadx.com)



[www.inovadx.com](http://www.inovadx.com)

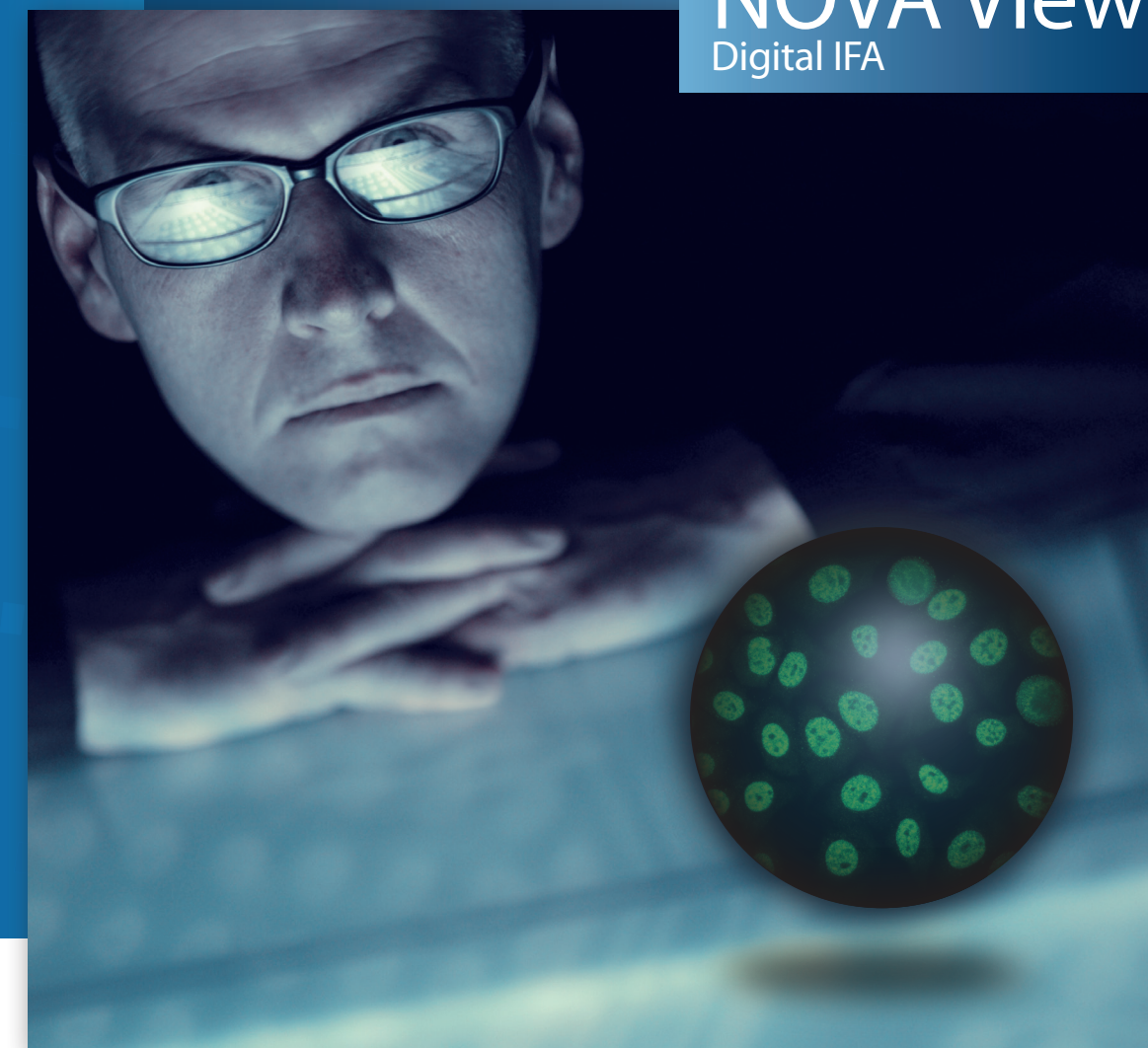
San Diego, CA 92131 USA  
PH: +1-858-586-9900 US Toll Free: 1-800-545-9495 FAX: +1-858-586-9911

BIO-FLASH is a registered trademark of Biokit, S.A. QUANTA Link, QUANTA-Lyser, NOVA View, NOVA Lite and QUANTA Flash are registered trademarks of Inova Diagnostics, Inc. © 2015 Inova Diagnostics, Inc. All rights reserved.

690141 July 2015 Rev. 5

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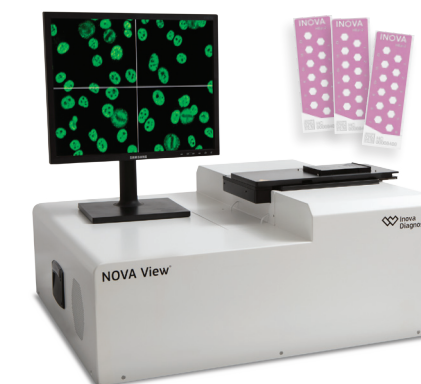
**NOVA View®**  
Digital IFA



# Confidence

Welcome to the world of digital IFA

**NOVA View is an automated digital IFA microscope for the detection of antinuclear antibodies (ANA) with indirect fluorescence assay (IFA) technology.**



- NOVA View automatically acquires and presents digital images of HEp-2 cells for operator review and confirmation
- NOVA View recognizes and displays mitotic cells and identifies five common ANA patterns
- Single well titer prediction can reduce IFA workload and lower material costs
- NOVA Lite® DAPI ANA Kit provides optimal clinical sensitivity and specificity, and excellent agreement with manual IFA
- DAPI stain provides built-in control to visualize cells in a negative well
- System calibration facilitates standardization

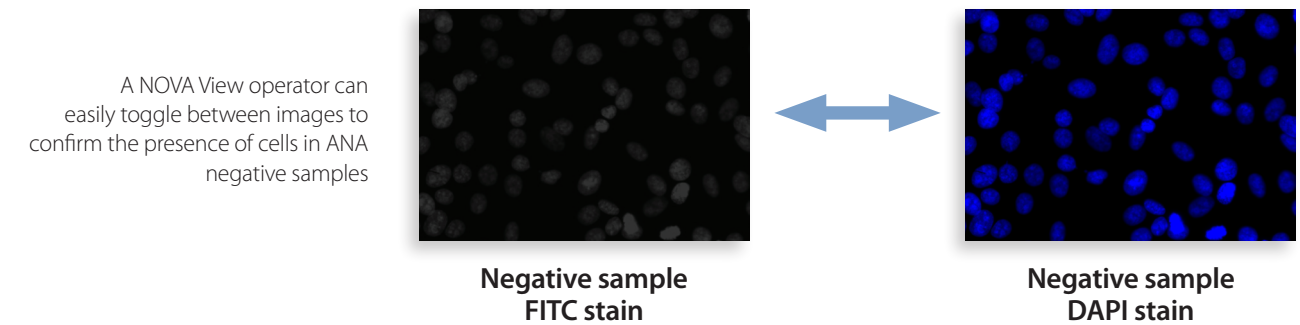
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# Image Analysis

## NOVA Lite DAPI ANA Kit uses DAPI stain for built-in control

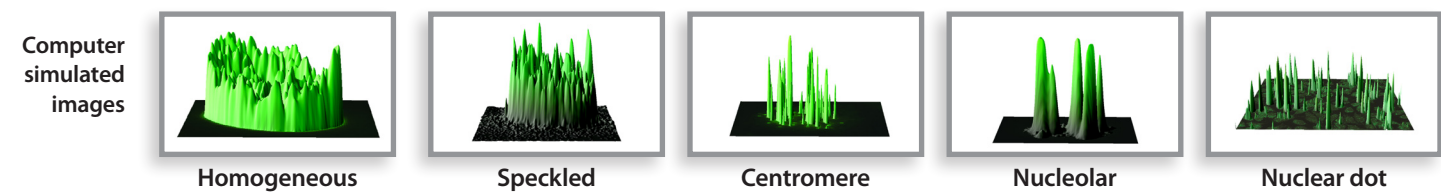
NOVA View differentiates a negative IFA sample from a well without HEp-2 cells. NOVA Lite DAPI ANA Kit allows for visualization of cells in negative wells.



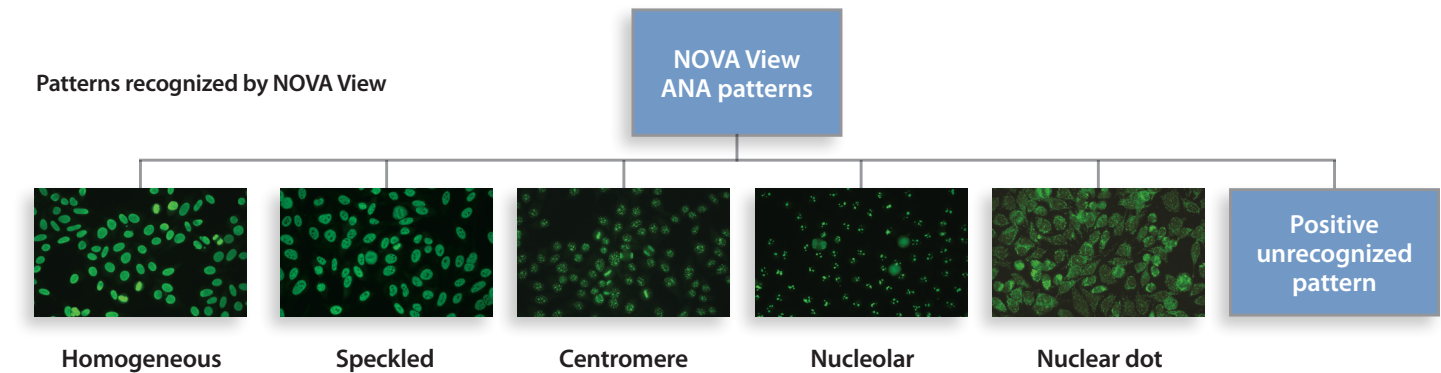
## NOVA View uses computer algorithms to provide consistent results

NOVA View uses digital technology to create images of stained HEp-2 wells, and computer algorithms to measure the nuclear light intensity within individual cells.

- NOVA View measures pixel intensity and light distribution, in a manner similar to the three-dimensional histograms below



- NOVA View algorithms identify five of the most common ANA patterns: homogeneous, speckled, centromere, nucleolar and nuclear dot
- NOVA View displays images of mitotic cells to facilitate ANA pattern confirmation

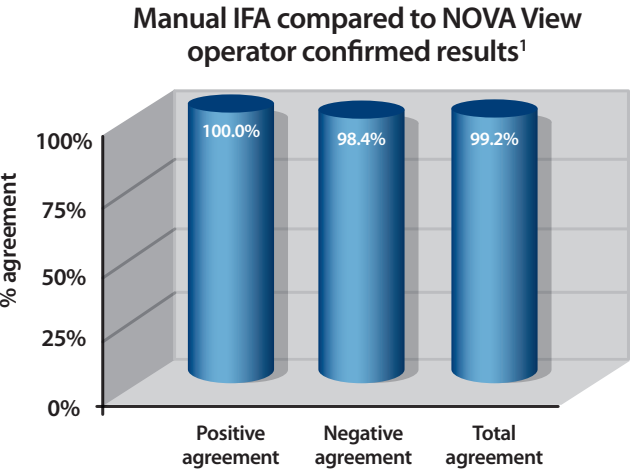


# Agreement with Manual IFA

## NOVA View offers excellent agreement with manual HEp-2 results

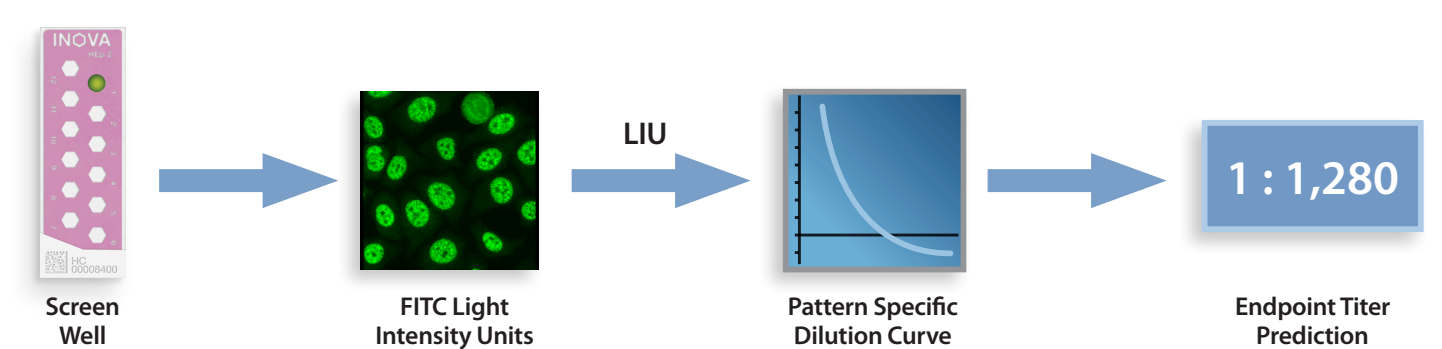
Proprietary slides are used to calibrate NOVA View instruments to provide consistent light intensity and image quality.

- 120 samples were tested to determine the level of agreement between NOVA View and manual HEp-2 results<sup>1,3</sup>
- This study confirms that results obtained by the operator reviewing NOVA View acquired images provide excellent agreement with reading performed on a manual IFA microscope

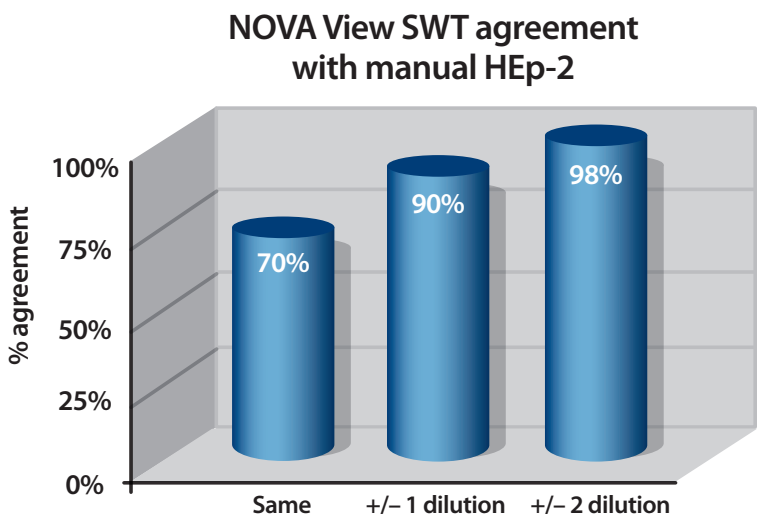


## NOVA View single well titer (SWT) prediction agrees with manual titer method

NOVA View uses pattern specific dilution curves to predict the endpoint titer of a sample using light intensity units (LIU) captured from the screening well. SWT endpoint prediction is available for the most frequent ANA patterns<sup>2</sup>



- NOVA View SWT prediction improves turn-around time, reduces hands-on time and lowers material costs compared to manual endpoint titer methods
- Pattern specific SWT prediction achieved 98% agreement with the manual method within +/- 2 dilutions<sup>3</sup>



# Clinical Performance Data

## NOVA Lite DAPI ANA Kit improves specificity without a significant reduction in sensitivity

NOVA Lite DAPI ANA Kit uses a 1:80 dilution to screen for ANA. 400 clinically characterized sera were evaluated at 1:40 and 1:80 dilutions to assess differences in clinical performance between screening dilutions.

- No significant difference in sensitivity was found using a 1:80 dilution based on the 95% confidence interval
- Significant improvement in specificity was seen with a 1:80 dilution compared to a 1:40 dilution

	Sensitivity <sup>3</sup> (95% CI)		Specificity <sup>3</sup> (95% CI)
Number of samples	Patients with SLE	Patients with SARD	Control population
	100	190	210
1:40 dilution	85.0% (76.5-91.4%)	78.4% (71.9-84.0)	74.4% (67.4-80.6)
1:80 dilution	81.0% (71.9-88.2%)	71.6% (64.4-77.9)	88.3% (82.7-92.6)

### Interpretation key:

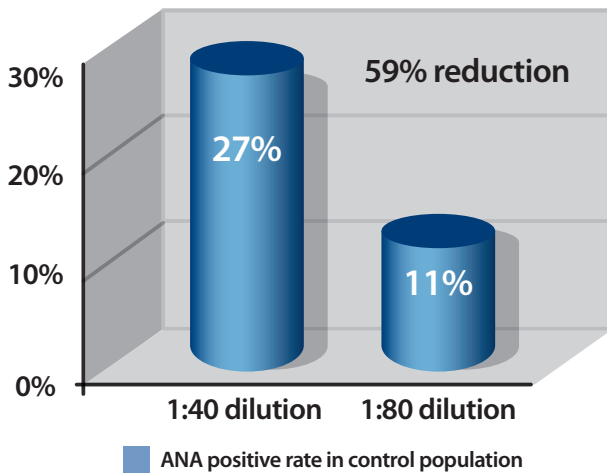
- SLE:** Systemic Lupus Erythematosus, **SARD:** Systemic Autoimmune Rheumatic Diseases (SLE+Sytemic sclerosis+Sjogren's Syndrome+Mixed Connective Tissue Disease+Autoimmune Myositis)
- The **control population** includes patients with infectious diseases, rheumatoid arthritis and healthy controls.

## NOVA Lite DAPI ANA Kit dramatically reduces the ANA positivity rate in the normal population

A screening dilution of 1:80 with NOVA Lite DAPI ANA Kit resulted in a 59% reduction of ANA positives detected in 150 apparently healthy subjects, from 27% in 1:40 dilution to 11% in 1:80 dilution.<sup>1</sup>

- The significant reduction of positive samples in a normal population improves the diagnostic utility of HEp-2 IFA testing and reduces the number of unnecessary follow up tests ordered

## NOVA Lite DAPI ANA 1:80 screening dilution reduces the positivity rate in the control population compared to 1:40 dilution



1. NOVA Lite DAPI ANA Kit direction insert  
2. NOVA View single well titer predictions are estimates only  
3. Data on file