# Economic Benefits

The Integrated Lab

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
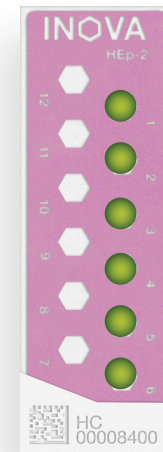
- **ANA screen:** Both methods require the same number of wells for screening

- **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
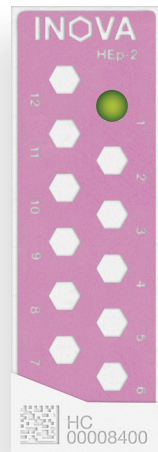
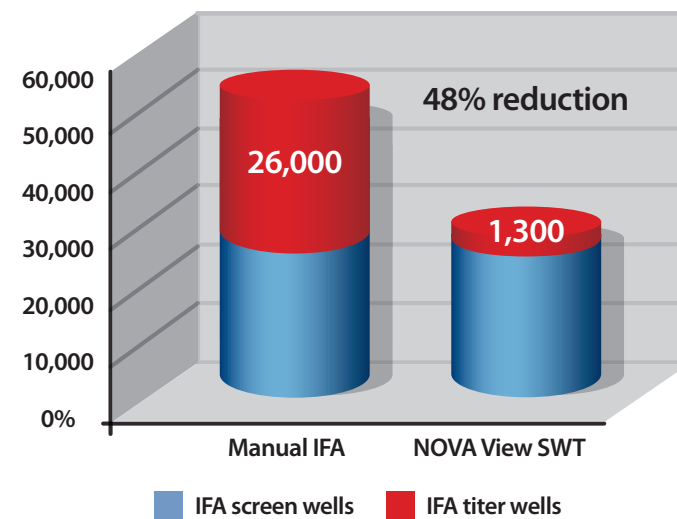| One well using NOVA View with SWT	VS.	Six wells using traditional manual IFA

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

NOVA View SWT reduces IFA workflow

48% reduction

	Manual IFA	NOVA View SWT
	26,000	1,300

- IFA screen wells
- IFA titer wells

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
- 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
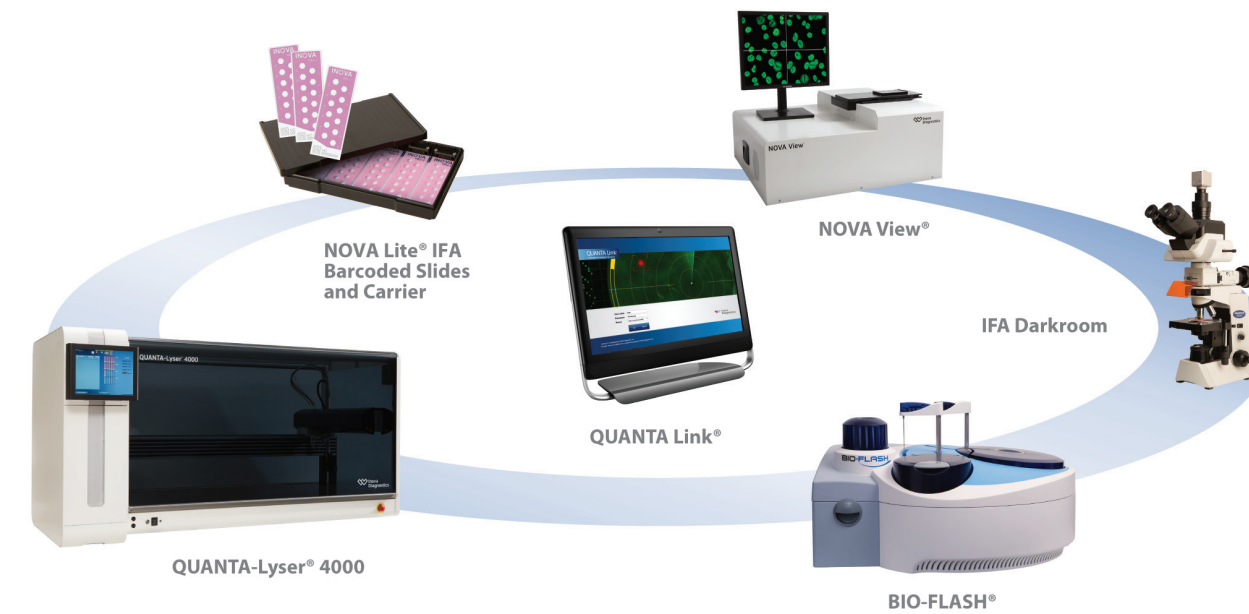
NOVA Lite® IFA
Barcoded Slides
and Carrier

NOVA View®

IFA Darkroom

QUANTA Link®

QUANTA-Lyser® 4000

BIO-FLASH®

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.**
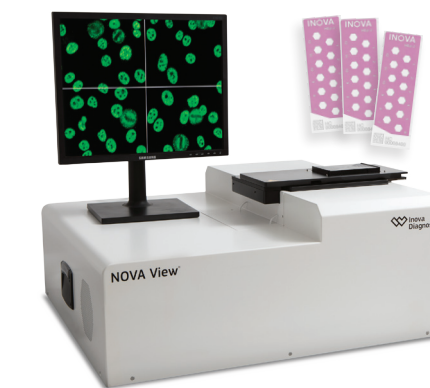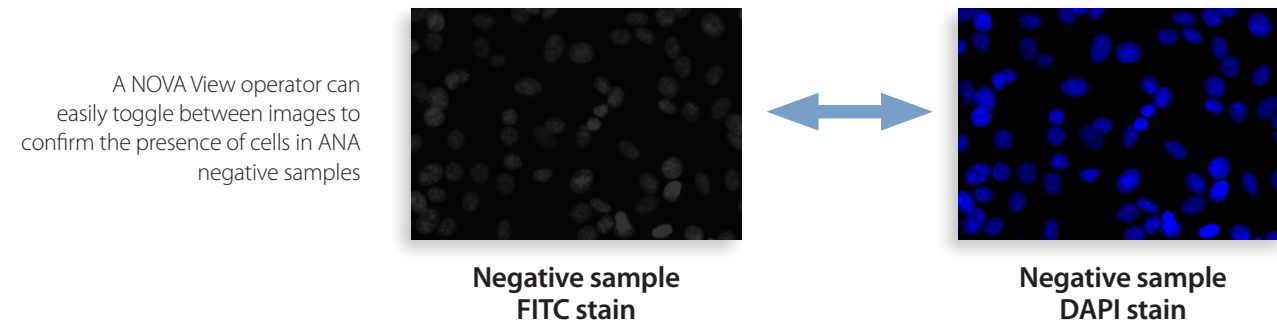

- NOVA View automatically acquires and presents digital images of HEp-2 cells for operator review and confirmation
- NOVA View recognizes and displays mitotic cells and identifies five common ANA patterns
- Single well titer prediction can reduce IFA workload and lower material costs
- NOVA Lite® DAPI 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

NOVA View

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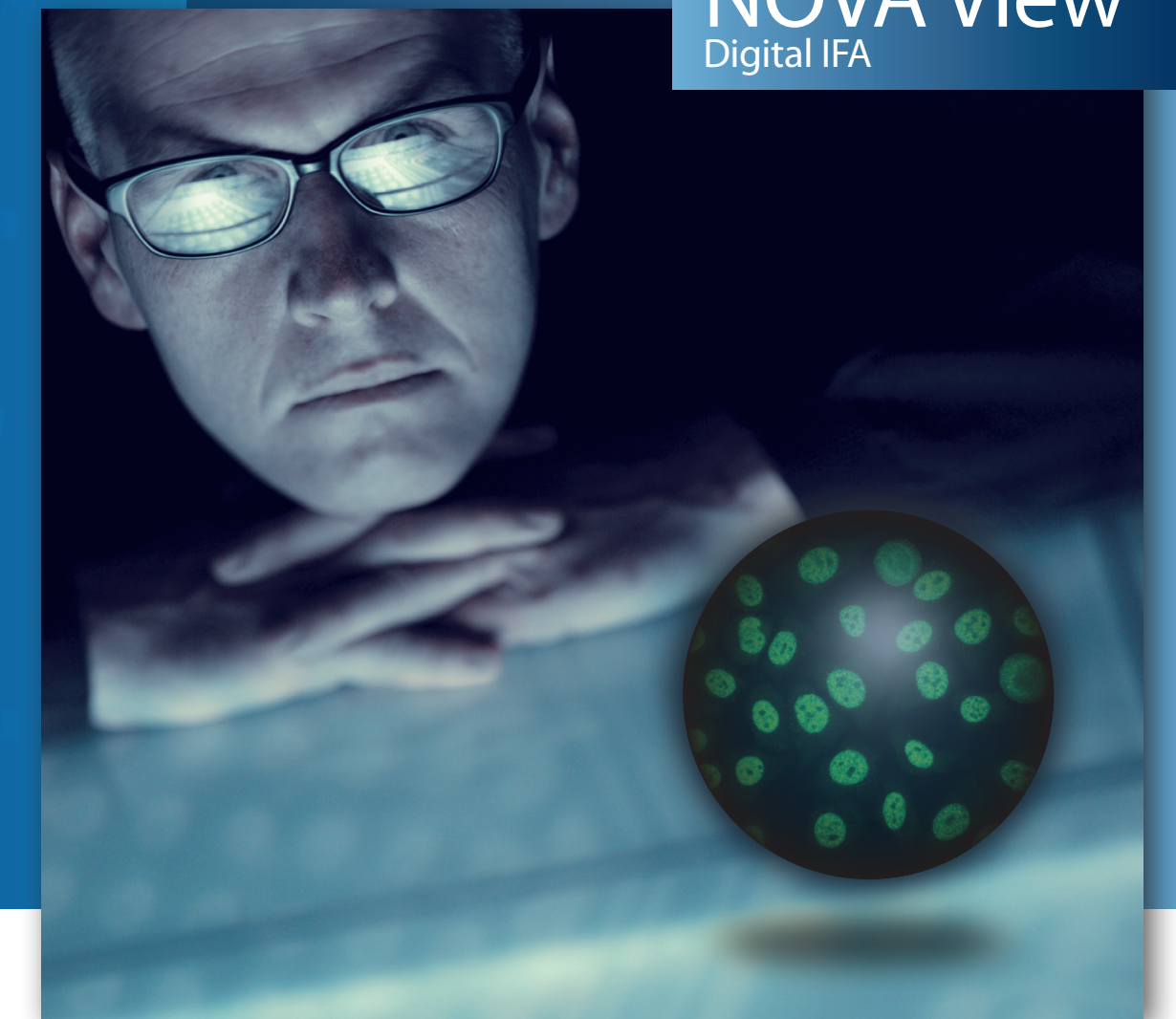
## NOVA Lite DAPI ANA Kit uses DAPI stain for built-in control

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.

A NOVA View operator can easily toggle between images to confirm the presence of cells in ANA negative samples

Negative sample FITC stain

Negative sample DAPI stain

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

Computer simulated images

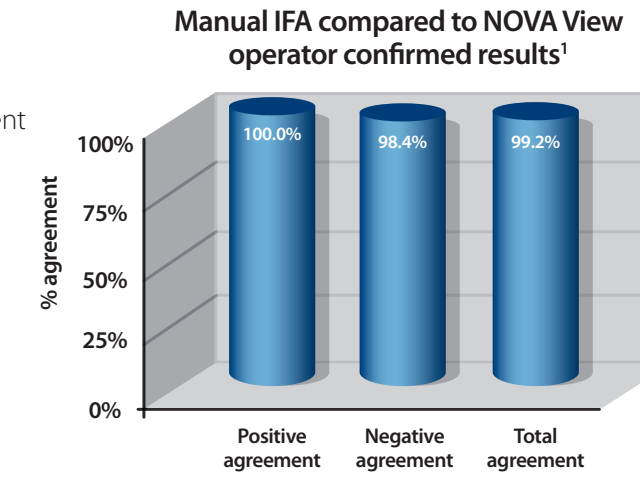| Homogeneous | Speckled | Centromere | Nucleolar | Nuclear dot |
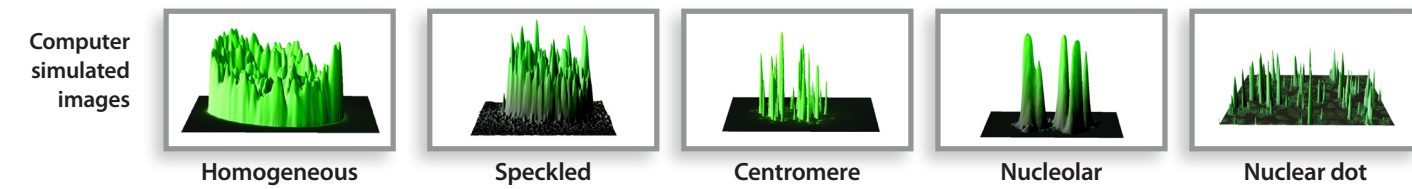
- NOVA View algorithms identify five of the most common ANA patterns: homogeneous, speckled, centromere, nucleolar and nuclear dot
- NOVA View displays images of mitotic cells to facilitate ANA pattern confirmation

Patterns recognized by NOVA View

NOVA View ANA patterns

| Homogeneous | Speckled | Centromere | Nucleolar | Nuclear dot |

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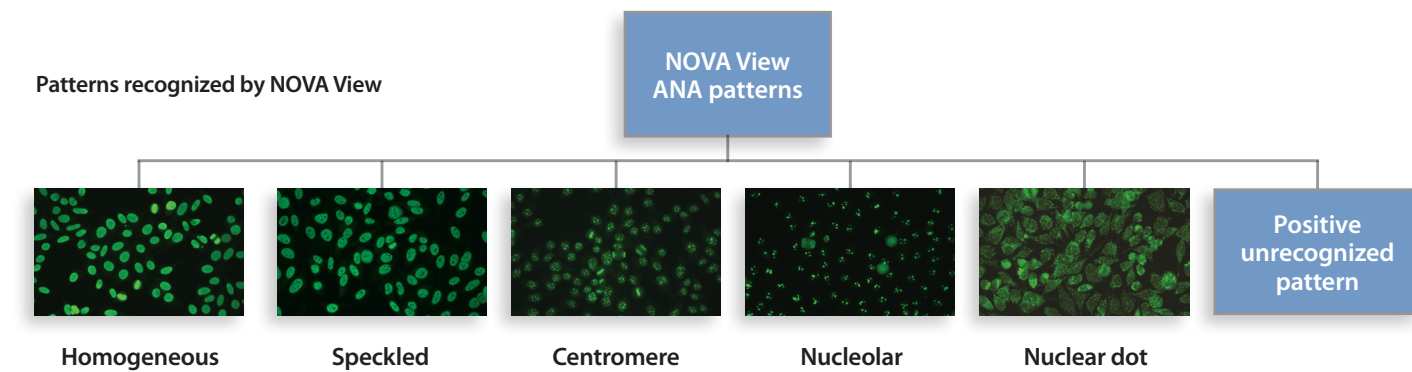
## NOVA View offers excellent agreement with manual HEp-2 results

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[1, 3]
- 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

Manual IFA compared to NOVA View operator confirmed results[1]

% agreement

- 100.0% Positive agreement
- 98.4% Negative agreement
- 99.2% Total agreement

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[2]

Screen Well → **FITC Light Intensity Units** → LIU → **Pattern Specific Dilution Curve** → **1 : 1,280** **Endpoint Titer Prediction**
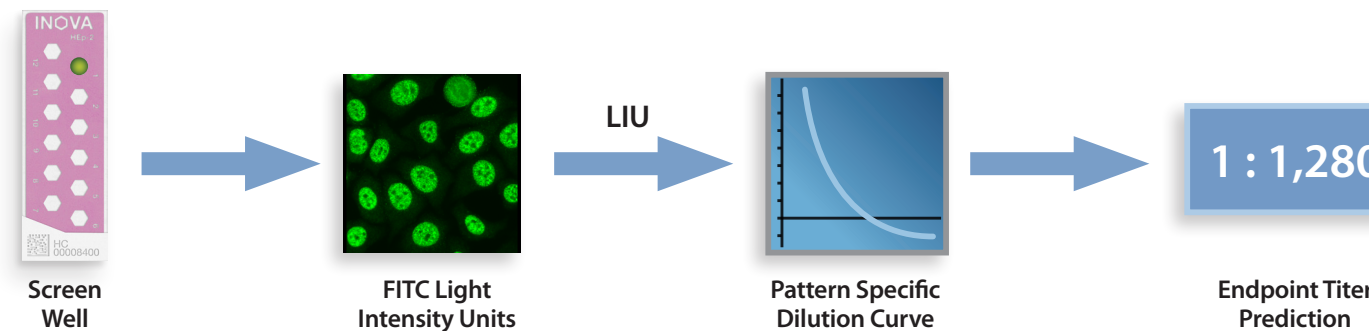
- NOVA View SWT prediction improves turn-around time, reduces hands-on time and lowers material costs compared to manual endpoint titer methods
- Pattern specific SWT prediction achieved 98% agreement with the manual method within +/− 2 dilutions[3]

NOVA View SWT agreement with manual HEp-2

% agreement

- 70% Same
- 90% +/− 1 dilution
- 98% +/− 2 dilution
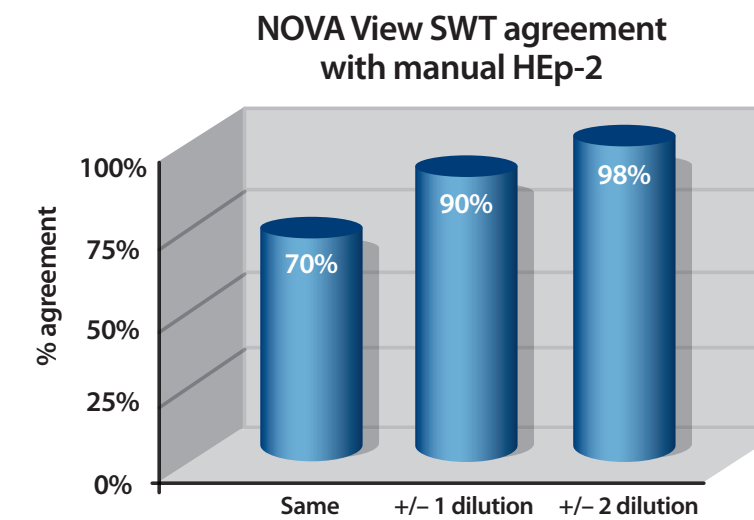
NOVA Lite DAPI ANA Kit improves specificity without a significant reduction in sensitivity

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[3] (95% CI)		Specificity[3] (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.[1]

- 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

- 27% 1:40 dilution
- 11% 1:80 dilution
- 59% reduction

■ ANA positive rate in control population
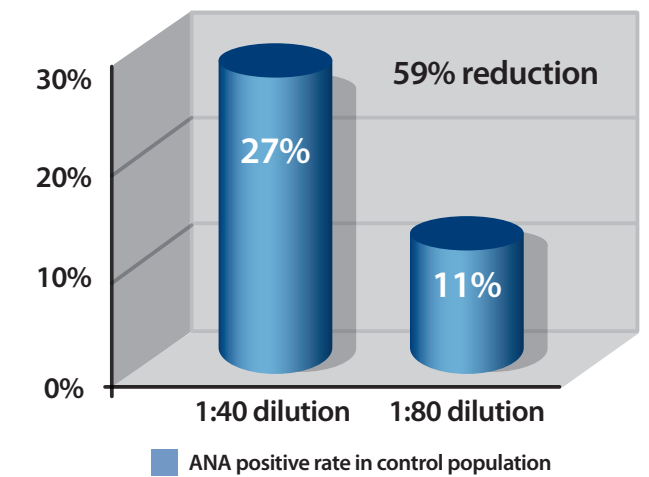
1. NOVA Lite DAPI ANA Kit direction insert
2. NOVA View single well titer predictions are estimates only
3. Data on file