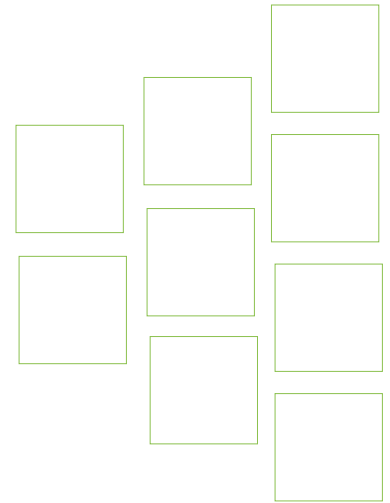


If **8%** of your positive ANAs don't look like this,
then you're missing something.

Something important.

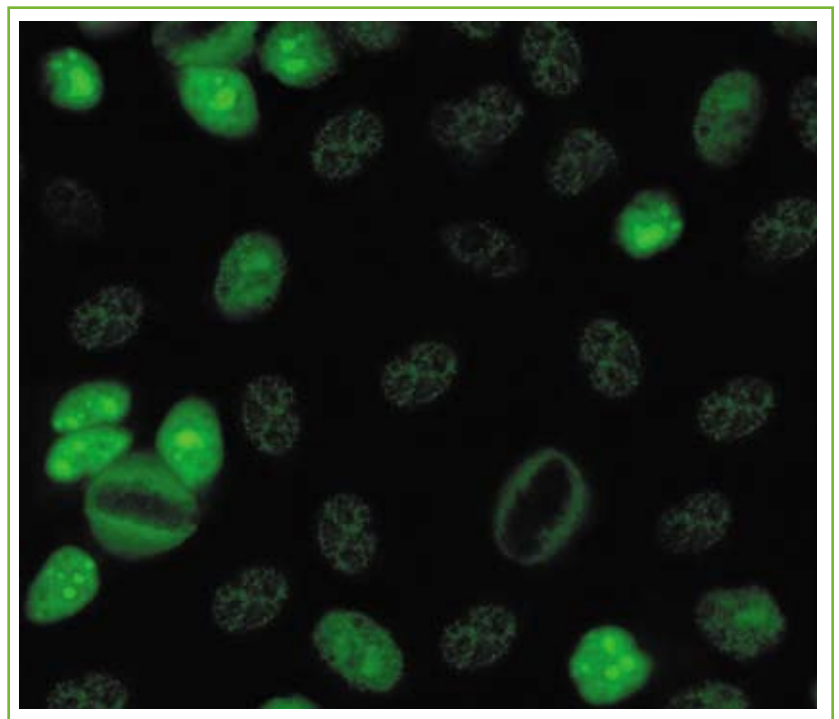
HEp-2000®

Still the **only** transfected ANA substrate!



A recent study identified anti-SSA/Ro antibodies as being present at least 3 years prior to a diagnosis of systemic lupus erythematosus being made.¹ Additional studies have reported anti-SSA/Ro antibodies are present in over 8% of ALL positive ANA samples tested.^{2,3} HEp-2000® is the **ONLY** slide-based ANA that can detect **AND** identify the presence of SS-A/Ro antibodies when the distinct SS-A/Ro pattern is seen.

“This new substrate detects SS-A/Ro antibodies that were not identified on standard HEp-2 substrates and by other immunoassays. The ability to detect SS-A/Ro antibodies with a single test should result in savings for the clinical laboratory and the health-care system.”⁴



1. Arbuckle, M. R., McClain M. T., et al., N Engl J Med, 349(16): 1526-1533, 2003.
2. Pollock, W., Toh, B.H., J Clin Pathol, 52:684-687, 1999.
3. Bossuyt, X., Meurs, L., Mewis, A., Mariën, G. and Blanckaert, N., Ann Clin Biochem, 37:216-219, 2000.
4. Fritzier, M.J. and Miller, B.J., J Clin Lab Anal, 9:218-224, 1995.



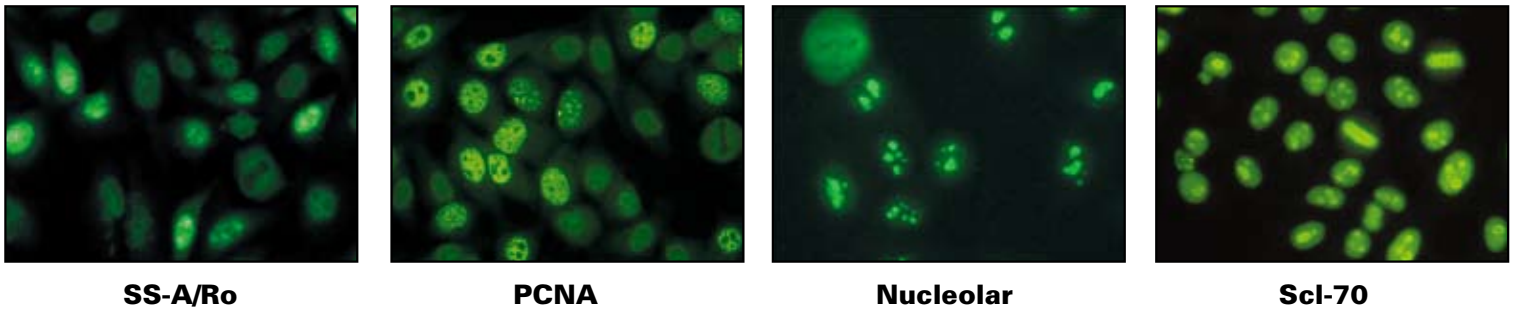
Reading and Reporting

All of the HEp-2000® cells are transfected with the information to hyperexpress the 60kD SS-A/Ro antigen. However, only about 10% - 20% of the cells demonstrate this hyperexpression. As a result, when anti-SS-A/Ro antibodies are the only ANAs present, one of two distinct patterns may be seen.

1. All of the cells demonstrate speckled staining of the interphase cells, and the 10% - 20% of cells hyperexpressing demonstrate stronger staining of the nucleus and/or nucleoli; some cells may show staining in the cytoplasm. This should be reported as ANA positive with two patterns present: speckled and the SS-A/Ro pattern. When the distinctive SS-A/Ro pattern is present it is considered confirmatory for the presence of SS-A/Ro antibodies. ENA testing is suggested to rule out the presence of autoantibodies to other ENAs.
2. Only the hyperexpressing cells demonstrate staining of the nucleus, nucleoli, and possibly the cytoplasm. The remaining interphase cells are negative. This should be reported as ANA positive, SS-A/Ro pattern present, and is considered confirmatory for the presence of SS-A/Ro antibodies. ENA testing is suggested to rule out the presence of autoantibodies to other ENAs.

The absence of the distinctive SS-A/Ro pattern does not rule out the possible presence of anti-SS-A/Ro antibodies. Studies have shown that approximately 90% of samples containing anti-SS-A/Ro antibodies will demonstrate the distinctive SS-A/Ro pattern while the remaining 10% are commonly ANA positive but do not produce the distinctive SS-A/Ro pattern.

When SS-A/Ro is present with other ANAs, it can be difficult to detect the distinct SS-A/Ro staining pattern. Upon titering, however, the characteristic SS-A/Ro pattern often becomes visible. When the SS-A/Ro staining does not appear and the presence of SS-A/Ro is suspected, the positive ANA should still be followed up with ENA testing and the SS-A/Ro may be detected at that point.



The images above show how the SS-A/Ro pattern is distinguishable from other ANA positive patterns on the HEp-2000® substrate. The SS-A/Ro pattern, above left, demonstrates the distinctive staining pattern seen on HEp-2000®. The nucleolar pattern, above center right, is easily differentiated from the SS-A/Ro because the nucleolar staining pattern is seen in every cell and there is no nuclear or cytoplasmic speckling. The Scl-70 pattern, above right, demonstrates a combination of homogeneous (positive chromosome area of the mitotics), speckled (fine speckling of the interphase cells) and nucleolar (staining in the nucleoli of most cells). The PCNA pattern, above center left, demonstrates cell cycle dependent staining similar to the SS-A/Ro; however, the PCNA lacks the nucleolar and cytoplasmic aspects of the SS-A/Ro pattern.

Ordering information:

		Slides x Wells
2040-Ro	HEp-2000® Fluorescent ANA-RoTest System	10 x 7
2100-Ro	HEp-2000® Fluorescent ANA-RoTest System	10 x 13
2200-Ro	HEp-2000® Fluorescent ANA-RoTest System	20 x 13
2200-14-Ro	HEp-2000® Fluorescent ANA-Ro Test System	20 x 14

Immuno Concepts' products are also available with an intense IgG-specific conjugate.
Bulk and custom packaging are available on standing order.

