

|      |   |   |
|------|---|---|
| Key: | >>> ... marks correct (expected) result               | N ... number of the results             |
|      | > ... marks conditionally correct (acceptable) result | Nrel ... relative number of the results |
|      | ± ... marks the result not evaluated                  |   |

**Test**

| Sample | Group | N | Result | N <sub>rel</sub> |
|--------|-------|---|--------|------------------|
|--------|-------|---|--------|------------------|

**Set 1****(560) ANA screening (cell nucleus) - prove**

|                          |             |                |                                    |       |
|--------------------------|-------------|----------------|------------------------------------|-------|
| A1                       | All results | >>>            | 20 Positive                        | 100 % |
| Total per sample: n = 20 |             | Success: 100 % |                                    |       |
| B1                       | All results | >>>            | 19 Negative                        | 95 %  |
|                          |             |                | 1 Inconclusive result (borderline) | 5,0 % |
| Total per sample: n = 20 |             | Success: 95 %  |                                    |       |
| Total success: 95 %      |             |                |                                    |       |

**(572) ANA screening (cell nucleus) - semi-quantity**

|                          |             |  |                            |       |
|--------------------------|-------------|--|----------------------------|-------|
| A1                       | All results | ±  | 1 titre 40                 | 8,3 % |
|                          |             | ±  | 2 titre 80                 | 17 %  |
|                          |             | ±  | 1 titre 160                | 8,3 % |
|                          |             | ±  | 1 titre 640                | 8,3 % |
|                          |             | ±  | 6 titre 1280               | 50 %  |
|                          |             | ±  | 1 titre 2560               | 8,3 % |
| Total per sample: n = 12 |             | Success (only evaluated results): evaluation |                            |       |
| B1                       | All results | ±  | 3 titre 0 (not measurable) | 25 %  |
|                          |             | ±  | 6 titre 40                 | 50 %  |
|                          |             | ±  | 3 titre 80                 | 25 %  |
| Total per sample: n = 12 |             | Success (only evaluated results): evaluation |                            |       |

**(561) ANA - type of fluorescence - nucleus**

|                          |             |               |   |       |
|--------------------------|-------------|---------------|---|-------|
| A1                       | All results | >>>           | 14 Centromere pattern                         | 88 %  |
|                          |             |               | 1 Centromere pattern; No fluorescence         | 6,3 % |
|                          |             |               | 1 Centromere pattern; Midbody pattern (MSA-2) | 6,3 % |
| Total per sample: n = 16 |             | Success: 88 % |   |       |
| B1                       | All results | >>>           | 1 Not specified                               | 6,3 % |
|                          |             |               | 15 No fluorescence                            | 94 %  |
| Total per sample: n = 16 |             | Success: 94 % |   |       |
| Total success: 81 %      |             |               |   |       |

**(563) ANA screening (cytoplasm) - prove**

|                          |             |                |             |       |
|--------------------------|-------------|----------------|-------------|-------|
| A1                       | All results | >>>            | 15 Negative | 94 %  |
|                          |             |                | 1 Positive  | 6,3 % |
| Total per sample: n = 16 |             | Success: 94 %  |             |       |
| B1                       | All results | >>>            | 16 Negative | 100 % |
| Total per sample: n = 16 |             | Success: 100 % |             |       |
| Total success: 94 %      |             |                |             |       |

**(573) ANA screening (cytoplasm) - semi-quantity**

|                          |             |  |                            |      |
|--------------------------|-------------|--|----------------------------|------|
| A1                       | All results | ±  | 4 titre 0 (not measurable) | 33 % |
|                          |             | ±  | 5 titre 40                 | 42 % |
|                          |             | ±  | 3 titre 80                 | 25 % |
| Total per sample: n = 12 |             | Success (only evaluated results): evaluation |                            |      |
| B1                       | All results | ±  | 3 titre 0 (not measurable) | 25 % |
|                          |             | ±  | 6 titre 40                 | 50 % |
|                          |             | ±  | 3 titre 80                 | 25 % |
| Total per sample: n = 12 |             | Success (only evaluated results): evaluation |                            |      |

**(564) ANA - type of fluorescence - cytoplasm**

|                          |             |                |                                     |       |
|--------------------------|-------------|----------------|-------------------------------------|-------|
| A1                       | All results | >>>            | 13 No fluorescence                  | 93 %  |
|                          |             |                | 1 Fine speckled cytoplasmic pattern | 7,1 % |
| Total per sample: n = 14 |             | Success: 93 %  |                                     |       |
| B1                       | All results | >>>            | 14 No fluorescence                  | 100 % |
| Total per sample: n = 14 |             | Success: 100 % |                                     |       |
| Total success: 93 %      |             |                |                                     |       |

**Set 2****(565) ANCA imunofluorescence - prove**

|                         |             |                |            |       |
|-------------------------|-------------|----------------|------------|-------|
| A2                      | All results | >>>            | 9 Positive | 100 % |
| Total per sample: n = 9 |             | Success: 100 % |            |       |
| B2                      | All results | >>>            | 9 Negative | 100 % |
| Total per sample: n = 9 |             | Success: 100 % |            |       |
| Total success: 100 %    |             |                |            |       |

**(574) ANCA IF (ethanol) - semi-quantity**

|    |             |   |            |      |
|----|-------------|---|------------|------|
| A2 | All results | ± | 1 titre 20 | 25 % |
|    |             | ± | 1 titre 80 | 25 % |

| Test  |             | N  | Result                            | N <sub>rel</sub> |
|---|-------------|--|-----------------------------------|------------------|
| Sample  | Group       |  |                                   |                  |
| A2  | All results | ± 1  | titre 160                         | 25 %             |
|   |             | ± 1  | titre 640                         | 25 %             |
| Total per sample: n = 4                         |             | Success (only evaluated results): evaluation |                                   |                  |
| B2  | All results | ± 1  | titre 0 (not measurable)          | 25 %             |
|   |             | ± 3  | titre 20                          | 75 %             |
| Total per sample: n = 4                         |             | Success (only evaluated results): evaluation |                                   |                  |
| <b>(578) ANCA IF (formalin) - semi-quantity</b> |             |  |                                   |                  |
| A2  | All results | ± 1  | titre 20                          | 25 %             |
|   |             | ± 1  | titre 80                          | 25 %             |
|   |             | ± 1  | titre 160                         | 25 %             |
|   |             | ± 1  | titre 320                         | 25 %             |
| Total per sample: n = 4                         |             | Success (only evaluated results): evaluation |                                   |                  |
| B2  | All results | ± 1  | titre 0 (not measurable)          | 25 %             |
|   |             | ± 3  | titre 20                          | 75 %             |
| Total per sample: n = 4                         |             | Success (only evaluated results): evaluation |                                   |                  |
| <b>(566) ANCA - type of fluorescence</b>        |             |  |                                   |                  |
| A2  | All results | >>> 8  | Cytoplasmic granular fluorescence | 100 %            |
| Total per sample: n = 8                         |             | Success: 100 %                               |                                   |                  |
| B2  | All results | >>> 8  | No fluorescence                   | 100 %            |
| Total per sample: n = 8                         |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(569) anti-myeloperoxidase</b>               |             |  |                                   |                  |
| A2  | All results | >>> 15                                       | Negative                          | 100 %            |
| Total per sample: n = 15                        |             | Success: 100 %                               |                                   |                  |
| B2  | All results | >>> 15                                       | Negative                          | 100 %            |
| Total per sample: n = 15                        |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(570) anti-proteinase III</b>                |             |  |                                   |                  |
| A2  | All results | 1  | Negative                          | 6,7 %            |
|   |             | >>> 14                                       | Positive                          | 93 %             |
| Total per sample: n = 15                        |             | Success: 93 %                                |                                   |                  |
| B2  | All results | >>> 15                                       | Negative                          | 100 %            |
| Total per sample: n = 15                        |             | Success: 100 %                               |                                   |                  |
| Total success: 93 %                             |             |  |                                   |                  |
| <b>Set 3</b>                                    |             |  |                                   |                  |
| <b>(580) Anti-ENA/SS-A/Ro-60</b>                |             |  |                                   |                  |
| A3  | All results | >>> 18                                       | Positive                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| B3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(581) Anti-ENA/SS-B/La</b>                   |             |  |                                   |                  |
| A3  | All results | >>> 18                                       | Positive                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| B3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(582) Anti-ENA/Scl-70</b>                    |             |  |                                   |                  |
| A3  | All results | >>> 17                                       | Negative                          | 100 %            |
| Total per sample: n = 17                        |             | Success: 100 %                               |                                   |                  |
| B3  | All results | >>> 17                                       | Negative                          | 100 %            |
| Total per sample: n = 17                        |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(583) Anti-ENA/RNP</b>                       |             |  |                                   |                  |
| A3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| B3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| Total success: 100 %                            |             |  |                                   |                  |
| <b>(584) Anti-ENA/Jo-1</b>                      |             |  |                                   |                  |
| A3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |
| B3  | All results | >>> 18                                       | Negative                          | 100 %            |
| Total per sample: n = 18                        |             | Success: 100 %                               |                                   |                  |

**Test**

| Sample | Group | N | Result | N <sub>rel</sub> |
|--------|-------|---|--------|------------------|
|--------|-------|---|--------|------------------|

Total success: 100 %

**(585) Anti-centromere antibodies**

|                          |             |                |               |       |
|--------------------------|-------------|----------------|---------------|-------|
| A3                       | All results | >>> 17         | Negative      | 100 % |
| Total per sample: n = 17 |             | Success: 100 % |               |       |
| B3                       | All results | 1              | Not specified | 5,9 % |
| Total per sample: n = 17 |             | >>> 16         | Negative      | 94 %  |
| Total per sample: n = 17 |             | Success: 94 %  |               |       |

Total success: 94 %

**Set 4****(588) Anti-ds-DNA immunofluores. - prove**

|                         |             |                |          |       |
|-------------------------|-------------|----------------|----------|-------|
| A4                      | All results | >>> 8          | Positive | 100 % |
| Total per sample: n = 8 |             | Success: 100 % |          |       |
| B4                      | All results | >>> 8          | Negative | 100 % |
| Total per sample: n = 8 |             | Success: 100 % |          |       |

Total success: 100 %

**(577) Anti-ds-DNA immunofluor. - semi-quantity**

|                         |             |  |                          |      |
|-------------------------|-------------|--|--------------------------|------|
| A4                      | All results | ± 1  | titre 10                 | 20 % |
|                         |             | ± 2  | titre 80                 | 40 % |
|                         |             | ± 1  | titre 160                | 20 % |
|                         |             | ± 1  | titre 320                | 20 % |
| Total per sample: n = 5 |             | Success (only evaluated results): evaluation |                          |      |
| B4                      | All results | ± 1  | titre 0 (not measurable) | 20 % |
|                         |             | ± 4  | titre 10                 | 80 % |
| Total per sample: n = 5 |             | Success (only evaluated results): evaluation |                          |      |

**(589) Anti-ds-DNA other methods**

|                          |             |                |                                  |       |
|--------------------------|-------------|----------------|----------------------------------|-------|
| A4                       | All results | >>> 10         | Positive                         | 100 % |
| Total per sample: n = 10 |             | Success: 100 % |                                  |       |
| B4                       | All results | >>> 9          | Negative                         | 90 %  |
|                          |             | 1              | Inconclusive result (borderline) | 10 %  |
| Total per sample: n = 10 |             | Success: 90 %  |                                  |       |

Total success: 90 %

**Set 5****(591) Anti-nucleosomes IgG**

|                          |             |                |          |       |
|--------------------------|-------------|----------------|----------|-------|
| A5                       | All results | >>> 11         | Positive | 100 % |
| Total per sample: n = 11 |             | Success: 100 % |          |       |
| B5                       | All results | >>> 11         | Negative | 100 % |
| Total per sample: n = 11 |             | Success: 100 % |          |       |

Total success: 100 %