

Coding and Reimbursement for Antinuclear Antibodies (ANA) and Extractable Nuclear Antibodies (ENA) Determined Using the BioPlex 2200

BioPlex 2200 Technology

The BioPlex 2200 immunoassay analyzer measures reactions occurring on the surface of microscopic (8 micron) polystyrene beads, each one having a unique color corresponding to the test being performed. Beads are introduced to a patient sample, and after processing, pass through a detector where each bead is measured separately. As the bead passes through the detector, it is first identified by its color then the amount of antibody bound to its surface is measured.

Since each bead functions as a separate assay, this technology has the unique ability to perform many different tests within a single reaction vessel by mixing a variety of beads, each coated with its respective antigen.

The ANA Screen kit was the first set of analytes released on the BioPlex 2200 analyzer. An ANA is the first line of testing for autoimmune disease. Positive results are typically followed up with ENA or other testing to further define the diagnosis.

This kit will allow the performance of an ANA screen or detect 11 different extractable nuclear antibodies (ENA's) used in systemic autoimmune disease testing. The ANA screen is based on a composite result of the 11 ENA beads.

Although all 11 tests are performed in one reaction vessel, they are all discrete reactions (procedures). For example, the beads used to detect antibodies to dsDNA have no impact or influence on the beads used to detect antibodies to Sm-RNP. If the dsDNA bead were not present, the BioPlex 2200 would still be able to provide the Sm-RNP result, and vice-versa. Thus results for any or all of the ENA antibodies may be ordered.

Software controls in the BioPlex 2200 prevent access to individual ENA results when only an ANA screen is ordered and performed. Individual ENA tests must be performed as a separate procedure.

CPT Coding

Anti-Nuclear Antibodies (ANA screen) are reported using the following CPT code:

86038 Anti-Nuclear Antibodies (ANA) Medicare Fee: \$16.89

Individual Extractable nuclear antigen (ENA) determinations for SSA, SSB, Scl-70, Jo-1, Chromatin, RNP, Smith, smRNP, Centromere B, and Ribosomal P antibodies are reported using the following CPT code once for each antibody tested;

86235 Extractable nuclear antigen, any method, each antibody

ds- DNA is reported separately using the following analyte-specific code:

86225 Deoxyribonucleic acid (DNA) antibody; native or double stranded

The above tests are often ordered as an ANA screen with reflex to selected individual ENA antibodies when the ANA screen is positive. Coding and Medicare reimbursement for a situation when a positive ANA results in reflex tests for all 11 available antibodies would be as follows:

86038 Anti-Nuclear Antibodies (ANA)

86225 Deoxyribonucleic acid (DNA) antibody; native or double stranded

86235 X10 Extractable nuclear antigen, any method, each antibody

Test Ordering and Test Requisition Design

It is important that only tests that have been clearly ordered by a physician be performed and reported. The following examples illustrate proper requisition formats for use in ordering BioPlex 2200 ANA and ENA tests. These formats allow physicians to choose any combination of tests or available panels and be fully aware how each test or panel will be billed (as indicated by the listed CPT codes).

Example 1: ANA with reflex based on positive ANA results:

- Anti-Nuclear Antibodies (ANA) without reflex (86038)
- Anti-Nuclear Antibodies (ANA) with reflex to ENA Panel or selected individual ENAs below when positive

ENA Panel (includes all of the following antibodies)

- ENA: SSA (86235)
- ENA: SSB (86235)
- ENA: Scl-70 (86235)
- ENA: Jo-1 (86235)
- ENA: Chromatin (86235)
- ENA: ds-DNA (86225)
- ENA: RNP (86235)
- ENA: Smith (86235)
- ENA: smRNP (86235)
- ENA: Centromere B (86235)
- ENA: Ribosomal P (86235)

Example 2: ANA without reflex option:

- Anti-Nuclear Antibodies (ANA)
- ENA Panel (includes all of the following antibodies)
- ENA: SSA (86235)
- ENA: SSB (86235)
- ENA: Scl-70 (86235)
- ENA: Jo-1 (86235)
- ENA: Chromatin (86235)
- ENA: ds-DNA (86225)
- ENA: RNP (86235)
- ENA: Smith (86235)
- ENA: smRNP (86235)
- ENA: Centromere B (86235)
- ENA: Ribosomal P (86235)

Other customized combinations of ENA tests can be included so long as the reflex criteria and resulting tests to be performed are clearly indicated either on the laboratory requisition or service manual.

The above coding and requisition design should result in the proper ordering of all ANA and ENA tests and comply with both the spirit and letter of Medicare rules and regulations regarding coding and medical necessity.

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