Erythrocyte Sedimentation Rate Survey

Kit Contents

Three specimens
- ESR-04 — ESR-06

Important: Before You Begin

New for this Mailing
None

Reporting Code Changes

Vacuette users: Codes 3407 Vacuette SRS series and 3408 Vacuette SRT series are no longer valid. Please report code 3276 Vacuette SRS, SRT series.

Storage and Stability Instructions
1. Remove material from shipping container and store the specimens at 2 - 8°C until testing can be performed.
2. The enclosed cold pack is intended to prevent specimens from encountering extreme temperatures during shipping.

Detailed Testing Instructions

For all instruments other than Ves-Matic instruments
1. For accurate test results, it is critically important to mix the specimen thoroughly.
2. Remove vials from the refrigerator and allow to warm at room temperature for 20 minutes before mixing.
3. Mix vials thoroughly prior to use.
   a. Hold vials horizontally between the palms of the hands and vigorously roll back and forth, occasionally inverting the vial. Do not shake the vial or use a mechanical mixer.
   b. Mix in this manner for 2 - 3 minutes or until the red cells are completely and uniformly suspended.
   c. Gently invert the vial end-to-end 10 times before sampling.

Important: See the Biohazard Warning at the end of these instructions.
Customer Contact Center 800-323-4040 option 1 (domestic), or 847-832-7000 option 1 (international)
4. Indicate whether the assay was run diluted or undiluted by filling the appropriate bubble on the result form.  
   **Important:** The test is considered undiluted if no fluid is introduced to these specimens during any steps of the testing process. If fluid is introduced to these specimens during the testing process, the sample has been diluted.

### Indications of Deterioration

After mixing, the product should be similar in appearance to fresh whole blood. In un-mixed vials, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration (eg, very dark supernatant) or unacceptable results may indicate deterioration. Do not use the product if deterioration is suspected.

### For Ves-Matic instruments only

1. For accurate test results, it is critically important to mix the specimen thoroughly.
2. Remove vials from the refrigerator and allow to warm at room temperature for 20 minutes before mixing.
3. Mix vials thoroughly prior to use.
   a. Hold vials horizontally between the palms of the hands and vigorously roll back and forth, occasionally inverting the vial. **Do not shake the vial or use a mechanical mixer.**
   b. Mix in this manner for 2-3 minutes or until the red cells are completely and uniformly suspended.
   c. Gently invert the vial end-to-end 10 times before sampling.
   d. Remove the stopper from a Vacu-Tec™ tube. **Do not discard diluent from the tube.**
   e. Using a transfer pipette, fill the Vacu-Tec™ tube to the fill line with the well-mixed sample.
   f. Stopper the Vacu-Tec™ tube and invert end-to-end 20 times.
4. Use the “Westergren 1 hr.” setting.
5. Verify that “diluted” is indicated on your methodology page, or fill the bubble for “diluted” next to the manufacturer code boxes on the result form.

### Reporting Your Results

#### General Reporting Instructions

1. Each mailing, verify the accuracy of your reporting codes (eg, manufacturer, method, instrument, reagent) by reviewing the online result form or the Method Summary Page attached to the front of your result form.
2. For any testing that you do not routinely perform in your laboratory, leave all reporting areas for that test blank unless otherwise noted.
3. Exception Codes: If you must report an analytical problem for a test or individual analyte, leave the result area blank and fill one of the following bubbles on the result form. Documentation on the use of these codes is the responsibility of the laboratory.
   - **11 Unable to analyze**
     Use code 11 to indicate why specimens were not analyzed; for example, “instrument not functioning,” “reagents not available,” etc.
   - **22 Result is outside the method/instrument reportable range**
     Use code 22 if you obtain a high or low result outside the reportable range of your method or instrument. Do not use this code if there is an option to fill a bubble for a “greater than” or “less than” result.
Per the Federal Register

- Proficiency Testing (PT) specimens must be tested with the laboratory’s regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens.
- If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number.
- Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number.

Disclaimer
Survey samples, their progeny, unmodified derivatives, or modifications thereof may not be transferred or incorporated into a product intended for sale. Survey samples, their progeny, unmodified derivatives, or modifications thereof, reagents, and disposable equipment used in proficiency testing, when disposed of, should be autoclaved or incinerated and disposed of as hazardous waste.

33 Specimen unsatisfactory
To use code 33, you must contact the CAP.

4. Corrections can be made at any time prior to the due date printed on the result form.
- Review all entries for accuracy prior to online approval or before sending by fax or mail.
- For results that are approved online, corrections must also be done online. Faxed or mailed corrections will not be accepted.

Submitting Results

1. Results must be received at the CAP no later than midnight, Central Time by the due date on the result form. Results cannot be accepted if received after the due date.
2. Your laboratory must establish a laboratory web account, referred to as “Opting In,” to submit results online. Information about opting in and a unique PIN was mailed to all laboratory directors. If your laboratory director does not have this information, please contact the CAP for a replacement letter.
3. Laboratory staff who will enter results online must first establish a personal web account. Once a personal web account is established, laboratory staff can request access to their laboratory’s information.

Biohazard Warning

All Survey samples should be treated as if potentially infectious and should be handled as if they are capable of transmitting disease.

Survey samples are prepared from blood or other source material obtained from human donors or animals.

When working with Survey samples, precautions should be taken to protect yourself and others from accidental exposure to infectious agents such as HIV, HBV, and HCV.

HIV can be transmitted through accidental parenteral inoculation, mucous membranes, or non-intact skin contact with HIV infected blood or body fluids. HBV and HCV can be transmitted through accidental parenteral inoculation, mucous membranes, non-intact skin contact, aerosolization or ingestion.

Precautions described in CDC and FDA recommendations and OSHA blood borne pathogen rules should be followed at all times when handling Survey samples and reagents.

Such precautions include the following:
- Gloves should be put on before opening the container and should be kept on throughout the period samples are handled. Replace gloves if contaminated, or if their ability to function as a barrier is compromised.
- At high altitudes, samples should be opened in a hood or biologic safety cabinet.
- There should be no eating, drinking, or smoking in the laboratory.
- Hands should be washed after removing gloves and before leaving the testing area.
- Survey samples and reagents should be kept in separate refrigerators from those containing blood or blood components for transfusion.
- Survey samples, reagents, and disposable equipment used in testing should be autoclaved or incinerated and disposed of as hazardous waste.

Warning: This Survey may contain chemicals known to the State of California to cause cancer and to cause birth defects or other reproductive harm.
If there has been an accident in which you have been exposed to the Survey's materials, please call the CAP Hot Line at 800-443-3244 (domestic) or 847-470-2812 (international) at any time.

**For Assistance**

For replacement materials, please contact the CAP within 10 calendar days of the ship date for information. **Provide your CAP number and contact information with all correspondence.**

Telephone: 800-323-4040 option 1 (Monday - Friday, 7:00 am – 5:30 pm Central Time)

International Participants: 847-832-7000 option 1

Email: contactcenter@cap.org

Website: www.cap.org

Address: CAP Surveys Program
325 Waukegan Road
Northfield, IL 60093-2750

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**Manufacturer Master List**

<table>
<thead>
<tr>
<th>Deleted codes</th>
<th>New/Updated codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3408 - Vacuette SRT series</td>
<td>3276 - Vacuette SRS, SRT series</td>
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<tr>
<td>3407 - Vacuette SRS series</td>
<td></td>
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</tbody>
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1889  Dispette II Disposable Pipet
1888  Dispette Pipet
1887  Disposable Westergren Blood Sedimentation Tube
1948  Disposable Wintrobe Blood Sedimentation Tube
3271  ESRA Analyzers
1337  HemaTechnologies ESR Stat 180
2851  HemaTechnologies ESR STAT Plus
1890  MicroSed ESR Test Kit (Ulster)
1938  Mini-Ves Analyzer
2991  Mini-Ves II Analyzer
3272  Monitor 20, 20E, 100, MIX-Rate
3273  Monitor S, J, J+
2751  Polymedco Sediten
3406  Sedifast 16
3123  Sedimat Westergren
1876  Sediplast Westergren
1878  Sediplast Wintrobe
3207  Sedi-Rate Westergren
1952  Seditainer
2586  Seditainer 1.8
1875  Seditube Wintrobe (marked only at fill line)
1873  Self Zeroing Westergren
1874  Self Zeroing Wintrobe
1893  StarrSed
2281  Streck ESR-Auto Plus
3239  Streck ESR-8
1932  Streck ESR-10 Manual Rack
1892  Vacuette Pipet for ESR Testing
3276  Vacuette SRS, SRT series
2977  Vital Diagnostics Excyte 10/M/Mini, Microsed
2982  Vital Diagnostics Excyte 20
2978  Vital Diagnostics Excyte 40
1891  Winpette Pipet for ESR Testing
0010  Other, specify on result form

Inclusion on this master list does not imply FDA approval.