COLLEGE of AMERICAN PATHOLOGISTS

J-A 2016
Kit Instructions

Comprehensive Transfusion Medicine, Educational Challenge, and Electronic Crossmatch Survey

J • JE1 • EXM

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Kit Contents

J	J-01R — J-06R / J-01S — J-05S
JE1	JE-07R and JE-07S
EXM	EXM-01 — EXM-03 (simulated donor units) EXM-01R — EXM-03R (corresponding red blood cells)

Important: The Kit Contents lists all possible orderable programs for this mailing. Your laboratory will only receive the programs it **ordered**.

Important: Before You Begin

New for this Mailing

1. The electronic crossmatching section of the result form has been updated. Please review the Detailed Testing Instructions section for details.
2. The **Anti-A1 identified** section of the result form has been deleted.

Reporting Code Changes

The following manufacturers have either deleted or updated codes for this mailing:

None

Storage and Stability Instructions

1. Store vials at 2 - 8°C.
2. The red blood cell suspensions should be tested within 14 days of receipt. **Perform testing as soon as possible.**

Critical Reporting Information

1. **Antibody Identification:** If your laboratory performs Antibody Identification, you must complete the Antibody Identification section of the result form, even if the screen was negative.
2. **Compatibility Testing:**
   - **Perform and record serologic results even if an ABO/Rh incompatibility is expected.** Incompatible crossmatches are included in the Survey to verify that your laboratory is proficient in detecting them.
   - **For the purpose of this proficiency testing (PT), serologic crossmatches must be performed.**

- If your laboratory performs antiglobulin crossmatches, they should be performed on this Survey if a specimen has an unexpected antibody present.
- If your laboratory only performs immediate spin crossmatches and refers all antiglobulin crossmatches for testing, fill the "Would refer this specimen for testing" bubble for that specimen.
- **Partial reporting of results for an analyte will lead to a reduced overall score for that analyte (for graded analytes only).**

3. ABO typing PT is required by CLIA (ie, graded challenge); however, subtyping of ABO antigens is not required (ungraded challenge). See the Detailed Testing Instructions for further information.
4. **Grifols users:** Follow the instructions detailed in the manufacturer's package insert.
5. **EXM Survey Participants:**
   - Before processing the J Survey specimens, carefully read the Electronic Crossmatch (EXM) directions.
   - Perform electronic crossmatch on your computer system even if ABO/Rh incompatibility is expected.

Program Notes

JE1 and/or EXM Survey (s) must be ordered in conjunction with the J Survey.

Detailed Testing Instructions

1. J-01R through J-06R contain approximately 2 mL of a 3 - 4% red blood cell suspension. J-01S through J-05S contain approximately 3 mL of serum.
2. The graded blood bank specimens represent separate individuals. The red blood cells have been separated from their sera and are designated J-01R through J-05R, and J-01S through J-05S, respectively.
3. JE-07R contains approximately 2 mL of a 3 - 4% red blood cell suspension. JE-07S contains approximately 3 mL of serum.
4. Gently resuspend cells by repeated inversion of vial. **Do not shake.** Washing the cells prior to use is not necessary.
5. Gel method (manual) users: Spin down the 3-4% red blood cell suspension and remove the supernatant. From the concentrated red cells obtained, aliquot the appropriate volume and convert it to the appropriate red cell suspension using your gel diluent according to your standard operating procedure.

ABO Group/Rh Type

1. A worksheet is included for your convenience. Circle the number that corresponds to the observed reaction. Interpretation of these results will indicate phenotypes that will be found in the ABO group list and Rh type list on the result form. **This worksheet does not need to be returned to the CAP, but should be kept for your laboratory's records.**
2. When a specimen's red cell and serum ABO typings do not correspond to each other, and you refer such specimen for testing, fill the bubble "Serum/Plasma and cell group do not agree; additional testing or sample required" in the ABO section on the result form (eg, if the red cells are positive for the B antigen but anti-B is present in the corresponding serum sample).
3. Subtyping of ABO antigens to identify A_1 or other weak subgroups of A or B is not routine practice and is not clinically relevant in many situations. As a result, not all laboratories routinely perform this testing. Those laboratories who do routinely

perform subtyping or who wish to utilize these proficiency samples can perform the testing and report their results. Data will be shown in the participant summary but these results will be considered educational and will not be graded. This will prevent situations whereby a participant correctly identifies the ABO blood type (eg, A) but incorrectly identifies the subtype (eg, A_1, A_2, or A subgroup) resulting in failure on the CLIA required proficiency testing.

4. The designation A_{sub} refers to red blood cells that are agglutinated by anti-A, but not by anti-A_1. Commonly, such red blood cells are described as A_2. However, for purposes of this Survey, we prefer the more precise designation of A_{sub} (A subgroup).

Antibody Identification

1. If your laboratory performs Antibody Identification, you must complete the Antibody Identification section of the result form, even if the screen was negative.
2. **For each specimen**, do **one** of the following:
   - Use the **master list** to report all antibodies detected/identified in your laboratory.
   - If no antibody is detected/identified, use code 184.
   - If your laboratory does not perform antibody identification in-house, and it is referred to a reference laboratory, use code 100.
   - If your laboratory's standard operating procedure is to send out all identified antibodies for confirmation before patient results are reported, use code 100, and **do not** report unconfirmed antibody.

Note: For those antibodies that you cannot rule out, note those in the "Use of Other" section on the result form.

Compatibility Testing

Use the AABB *Technical Manual* definition for criteria used in grading positive results. These results are listed on the report but are not evaluated.

Identification of Antigens

1. Although results are not evaluated by the CAP, these tests are required by some states. Check your state requirements.
2. Perform testing for C, E, c, and e. It is suggested that anti-e be used only on cells that are E positive.
3. Three sets of boxes are provided for recording other red cell antigens. Do **not** report your CcEe Red Cell Antigen results in this section. Based upon your findings in the antibody study and crossmatches, test for the appropriate antigens. Using the Antibodies/Antisera Master List, enter the code of the antisera used on the result form.

Electronic Crossmatch (EXM)

Patient (J specimens)

1. If you are entering PT results "LIVE" for the first time, we recommend that you contact Medical Records and Billing departments to avoid any confusion when the medical record is created.
2. Enter your J-A 2016 results "LIVE" into your Laboratory Information System (LIS). If you are unable to enter your results "LIVE," into your LIS, you may enter them into the "Test Mode" but only if the "Test Mode" has the ability to perform an electronic crossmatch.

3. For laboratories that share the same LIS with a network of laboratories, we highly recommend that you uniquely identify the J-A Survey specimens to avoid the accidental sharing of PT results. For example, instead of entering specimen number J-01, assign a unique number that only your facility can identify.
4. Perform and enter ABO recheck (second type) on specimens J-01R, J-03R, and J-04R into your LIS.
5. If your laboratory requires two different specimens for ABO in order to perform electronic crossmatch, for PT purposes, pour off the J specimen in a different tube and perform appropriate testing.

Donor

1. Three unique, ISBT-128 labeled, simulated donor units, EXM-01 – EXM-03 have been provided along with their corresponding red cells for Unit ABO/Rh confirmation.
2. The **CAP ISBT-128 Facility Identification Number (FIN) is A9901.** Contact your information technology (IT) staff to ensure that your LIS is able to identify this number when scanning the simulated donor units.
3. Each simulated donor unit will contain a unique donation identification number (DIN).
4. Scan simulated donor units into your inventory as you would with a typical donor unit.
5. If you are unable to scan the simulated donor units into your LIS, we recommend entering the units manually.

Testing

1. Perform Unit ABO/Rh confirmation per your laboratory procedure.
2. Determine whether the patient specimen is eligible or ineligible for an electronic crossmatch based on the results of their alloantibody detection results. Record your results in the **Eligibility for Crossmatching (based on alloantibody results)** reporting area.
   a. Filling the bubble for "Patient sample eligible for electronic crossmatching" indicates that the specimen contains no alloantibody(ies).
   b. Filling the bubble for "Patient sample ineligible for electronic crossmatching" indicates that the specimen contains alloantibody (ies).
3. Perform the electronic crossmatch for the patient specimens that are eligible. This is to test your computer's ability to detect ABO compatibility.
   a. Allocate unit EXM-01 to specimen J-01 and perform electronic crossmatch.
   b. Allocate unit EXM-02 to specimen J-03 and perform electronic crossmatch.
   c. Allocate unit EXM-03 to specimen J-04 and perform electronic crossmatch.
4. If the specimen is ineligible, fill the bubble for code 216 (Not performed/system detected ineligibility).

Additional EXM Information

1. If your LIS requires a Registration Number such as Food and Drug Administration (FDA) established identifier (FEI) or central file numbers (CFNs) in order to bring donor units into your inventory, insert 999's as appropriate.
2. If you are unable to scan the unit in your inventory due to check digit, visit www.iccbba.org to confirm the check digit on the donor unit.
   a. Visit www.iccbba.org
   b. Select **Lookup Tools.**
   c. Select **Quick K Calculator.**
   d. Select **Quick K Calculator program.**
   e. When prompted to Run or Save file, choose **Run.**
   f. If prompted further, choose **Run** again.
   g. Enter the A9901xxxxxxxx number sequences.

Per CLIA, as published by the United States 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 specimens, their progeny, unmodified derivatives, or modifications thereof may not be transferred or incorporated into a program intended for sale. Survey specimens, their progeny, unmodified derivatives, or modifications thereof, reagents, and disposable equipment used in PT, when disposed of, should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

Reporting Your Results

General Reporting Instructions

1. **All laboratories subject to Clinical Laboratory Improvement Amendments (CLIA) regulations:** If your laboratory is discontinuing testing on any CMS-regulated analyte, you must check your **CMS Analyte Reporting Selections** to ensure no changes are needed. You can maintain your laboratory's current reporting preferences by accessing the application via e-*LAB* Solutions Suite.
2. 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.
3. The inclusion of reporting codes on the result form does not imply US FDA approval.
4. For any testing that you do not routinely perform in your laboratory, leave all reporting areas for that test blank unless otherwise noted.
5. **Exception Codes:** If you must report an analytical problem for a test or individual analyte, **leave the result area for that section blank** and fill one of the following bubbles on the result form within that section. The exception code bubble that you fill in will apply **only** to the result area(s) left blank. Documentation on the use of these codes is the responsibility of the laboratory and should be kept internally.
   - **11 Unable to analyze**
     Use code 11 to indicate why specimens were not analyzed (eg, instrument not functioning, reagents not available).
   - **33 Specimen unsatisfactory**
     To use code 33, you **must** contact the CAP.

   If you fill an exception code bubble **and** enter data on the result form, the data will be graded.
6. 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 specimens should be treated as if potentially infectious and should be handled as if they are capable of transmitting disease.

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

When working with Survey specimens, 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 specimens and reagents.

Such precautions include the following:

- Gloves should be put on **before opening the container** and should be kept on throughout the period specimens are handled. Replace gloves if contaminated, or if their ability to function as a barrier is compromised.
- At high altitudes, specimens 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 specimens and reagents should be kept in separate refrigerators from those containing blood or blood components for transfusion.
- Survey specimens, reagents, and disposable equipment used in testing should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

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 001-847-470-2812 (international) at any time. You can access Safety Data Sheets (SDS/MSDS) by logging on to cap.org, clicking on the Laboratory Improvement tab, then Catalog and Ordering Information.

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.** Participants in countries serviced by a designated CAP distributor should contact their distributor's customer service department.

Telephone: 800-323-4040 option 1
(Monday - Friday, 7:00 AM – 5:30 PM US Central Time)
International Participants: 001-847-832-7000 option 1

Email: contactcenter@cap.org
Website: cap.org

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

Manufacturer Master List

Deleted codes	New/Updated codes
None	None

125	Laboratory developed	115	DBL NOVACLONE Blood Grouping Reagent	121	Ortho-Clinical Diagnostics
113	Alba Bioscience (Quotient Biodiagnostics)	123	Grifols	112	Siemens
120	American Red Cross	119	Immucor	111	Selected cells from any of these in this list
183	Bio-Rad /DiaMed	118	Medion Diagnostics	010	Other manufacturer, specify on result form

ABO Method Master List

Deleted codes	New/Updated codes
None	None

29	Column Agglutination (Gel Testing)	27	Solid Phase Red Cell Adherence	01	Other, specify on result form
28	Liquid Micro Well Testing	26	Tube Testing		

Antibody/Antisera Master List

Unexpected Antibody(s) **identified as:**

146	Anti-Bg^a	124	Anti-K	131	Anti-Le^a	152	Anti-U
112	Anti-D	125	Anti-k	132	Anti-Le^b	150	Anti-Di^a
113	Anti-C	126	Anti-Fy^a	133	Anti-P$_1$	147	Antibody to other (nonlisted) high incidence antigen
163	Anti-G	127	Anti-Fy^b	134	Anti-M		
114	Anti-c	128	Anti-Jk^a	135	Anti-N	148	Antibody to other (nonlisted) low incidence antigen
115	Anti-E	129	Anti-Jk^b	136	Anti-S		
116	Anti-e	130	Anti-Kp^a	137	Anti-s	149	Warm autoantibody, specificity unknown
119	Anti-C^w	252	Anti-Kp^b	144	Anti-Wr^a	010	Other, specify on result form

EXM LIS Master List

Deleted codes	New/Updated codes
None	None

450	Blood Bank Computer Systems Blood Bank Control System	455	McKesson Horizon Blood Bank	462	Psyche Systems Corp. Systematic Blood Bank (SBB)
451	Cerner Corp. Cerner Millennium PathNet Blood Bank	456	Medical Information Technology Blood Bank System-6.0	463	SCC Soft Computer SoftBank II
452	Haemonetics Software Solutions (Wyndgate Technologies) ElDorado Donor	457	Medical Information Technology Blood Bank-client/server	464	SCC Soft Computer SoftDonor
453	Haemonetics Software Solutions (Wyndgate Technologies) SafeTrace	458	Medical Information Technology Blood Bank-Magic	465	Sunquest Information Systems (formerly Misys) Laboratory Blood Bank and Blood Bank Modules
454	Haemonetics Software Solutions (Wyndgate Technologies) SafeTrace Tx	459	Mediware Information Systems (Hemo-care/LifeLine) HCLL Transfusion	010	Other, specify
		460	Mediware Information Systems LifeTrak		
		461	NetLims LLC AutoFusion		

J-A 2016 Worksheet

ABO Group/Rh Type Worksheet

Specimen	Anti-A	Anti-B	Anti-A_1	Anti-A,B	A_1 Cells	B Cells	Anti-D	D control	ABO Group	Rh Type
J-01R (cells)	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG			1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	Fill in your code on the result form.	Fill in your code on the result form.
J-01S (serum)					1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG				
J-02R (cells)	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG			1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	Fill in your code on the result form.	Fill in your code on the result form.
J-02S (serum)					1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG				
J-03R (cells)	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG			1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	Fill in your code on the result form.	Fill in your code on the result form.
J-03S (serum)					1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG				
J-04R (cells)	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG			1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	Fill in your code on the result form.	Fill in your code on the result form.
J-04S (serum)					1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG				
J-05R (cells)	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG			1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG	Fill in your code on the result form.	Fill in your code on the result form.
J-05S (serum)					1. NT 2. POS 3. NEG	1. NT 2. POS 3. NEG				

Do not return to the CAP.