Keywords: clinitek, clinitest, hCG, pregnancy, urine

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I. PURPOSE

This procedure provides instructions for performing qualitative urine pregnancy testing using the Clinitest hCG Pregnancy Test cassettes on the Clinitek Status+ Connect System. The Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotropin (hCG) in urine specimens.

II. ORDER

A physician's order, standard protocol, or order by another health professional authorized to request laboratory testing is required for point-of-care qualitative urine pregnancy testing.

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III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents/Controls</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens Clinitest hCG Cassettes and Pipettes (25/box)</td>
<td>SAP Item #118248</td>
</tr>
<tr>
<td>Quantimetrix Dropper Plus Urinalysis Dipstick Controls (Levels 1 &amp; 2) and Package Insert</td>
<td>SAP # 32234</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinitek Printer Paper</td>
</tr>
<tr>
<td>Disposable Gloves</td>
</tr>
<tr>
<td>Alcohol Wipes</td>
</tr>
<tr>
<td>Gauze</td>
</tr>
<tr>
<td>Sterile Urine Collection Containers</td>
</tr>
<tr>
<td>Open Dating Labels</td>
</tr>
<tr>
<td>Hospital Approved Disinfectant Wipes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinitek Status+ Analyzer</td>
</tr>
<tr>
<td>Clinitek Status Connect Base</td>
</tr>
<tr>
<td>Handheld Barcode Reader</td>
</tr>
<tr>
<td>AC Power Cord and Interface Cables</td>
</tr>
<tr>
<td>Test Table and Test Table Insert</td>
</tr>
</tbody>
</table>
IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens Clinitest hCG Cassettes</td>
<td>Refrigerated or Room Temperature (2-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Quantimetrix Dropper Plus Urine Controls (Levels 1 &amp; 2)</td>
<td>Refrigerated (2-8°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td></td>
<td>Room Temperature (18-30°C)</td>
<td>One month or manufacturer's expiration date, whichever comes first.</td>
</tr>
<tr>
<td>Clinitek Status+ Connect System</td>
<td>Room Temperature (18-30°C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A. Once a box of cassettes is opened, it is required that the box is labeled with the open date.
B. If stored refrigerated, bring controls to room temperature for 15-30 minutes prior to use.
C. Once controls are brought to room temperature, it is required that they are labeled with the open date and new expiration date.
   1. If returned to the fridge immediately following use, only the open date must be labeled on the QC bottles.
D. Never use cassettes or controls past their expiration date.

V. SPECIMEN TYPE

A. A freshly voided urine sample may be collected at any time of day in a clean, dry container.
   1. NOTE: First morning urine samples will contain the highest concentration of hCG.
B. This assay requires approximately 200 µL for a single test.

VI. SPECIMEN COLLECTION AND HANDLING

A. The urine collection container must be labeled with at least two unique patient identifiers in the presence of the patient (e.g. Name, DOB, MRN, CSN).
B. All labeling must be done on the cup rather than the lid, which may become separated from the specimen.
C. Specimens that cannot be tested immediately should be sent to the core laboratory for testing.

VII. INTERFERING SUBSTANCES

See the Siemens Clinitest® hCG Instructions for Use (Appendix A) for additional information. In all Interference Testing performed, the pH of the urine did not affect the outcome.

VIII. SAFETY PRECAUTIONS

A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Transmission-based Isolation Precautions.
B. All patient specimens, QC materials, and reagent cassettes after use must be considered potentially infectious, handled with care, and disposed of in a JHMI-approved receptacle.
C. Refrigeration used for patient specimens and QC material is to be used only as designated.
   1. Temperatures are to be monitored, and documentation of that monitoring must be kept readily available for review.
IX. PERFORMING QUALITY CONTROL (QC) TESTS

A. Internal quality controls:
   1. Each test cassette includes two procedural controls, which indicate that sufficient sample was added for capillary flow to occur (Control (C) Region) and the correct procedural technique was used (Reference (R) Region).
   2. If the instrument detects a failure with either of these two procedural controls, an error will appear on the analyzer screen and the test must be repeated. Refer to D. for Corrective Action steps.

B. Two levels of external Quality Control, normal (Level 1) and abnormal (Level 2), are required:
   1. At least once a week on each instrument in use.
   2. When opening a new lot and/or shipment of cassettes.
   3. When patient results are questionable.
   4. By all new operators as part of initial hands-on training prior to testing patient specimens.
   5. At least once a year by each operator to maintain competency.

C. Procedure:
   1. Prepare QC and Clinitest cassette:
      a. Verify that controls and Clinitest cassette kits are dated and within both the manufacturer's expiration date and the open expiration date, as applicable.
      b. If QC solutions have been stored refrigerated, allow them to come to room temperature for at least 15 minutes.
   2. Prepare the analyzer:
      a. If the Clinitek Status+ Connect System is turned off, press and hold the button until the analyzer powers on.
      b. The test table will emerge and the system will complete a self-test.
      c. Observe the computer icon at the top left of the display screen. If an "X" appears on the computer icon , wait for the "X" to disappear (this may take a minute or two).
      d. Every seven (7) days, the Clinitek Status+ Connect System executes QC lockout.
         i. If QC is due (system locked), the Cassette Test icon will appear as a small rectangle at the lower left edge of the screen. Both levels of QC must be successfully completed prior to the analyzer allowing patient testing.
   3. Enter QC and cassette information into the analyzer:
      a. Touch "QC Test Due" on the display.
      b. Select "QC Cassette Test".
      c. Scan JHED ID barcode at the prompt for "Operator ID", then select Enter. Alternately, you can manually enter your JHED ID.
      d. Select "Enter lot and expiration date". Refer to the information on the left-hand side of the screen to review which level of control must be tested.
      e. Scan the lot number from the control bottle, then select Enter.
      f. Enter the room temperature expiration date, or manufacturer's expiration if stored refrigerated, for the control (Year, Month, Day) using the up and down arrows, then select Enter.
      g. Select "Enter new lot and expiration date" for the cassette.
h. Scan the barcode on the back of the cassette package to pull in both.

4. Perform the test:
   a. Ensure the test table insert is positioned for the hCG cassette (see Figure 1).
   b. Gently mix the control solution by inverting several times.
   c. Open the cassette package and place the cassette in the test table insert.
   d. Remove the QC vial cap.
   e. Touch "START" on the analyzer.
   f. Holding the QC vial vertically, place 4 drops of QC solution into the sample well of the cassette (see Figure 2).
   g. Eight (8) seconds after touching the "START" icon, the table will retract.
      i. NOTE: If the cassette is not properly placed or the QC solution has not been applied when the test table retracts, do not try to interfere. Wait until the error message displays on the screen and continue testing using a new cassette.
   h. Recap the QC vial and set it aside.
   i. Upon completion, the test table will emerge and the result will display on the screen as "PASS" or "FAIL".
      i. Results will be available anywhere between 2 and 5 minutes.
   j. Remove and discard the cassette in the proper waste container.
   k. Select "Done".
   l. Repeat steps 3d through 4k for the second level of control, as indicated by the analyzer.
   m. Both levels of QC must pass before patient testing can be performed.

5. After selecting "Done" following completion of both controls, a QC Results Summary screen will appear. If both levels of QC have passed, "Done" must be selected a second time.

D. If results fall outside the acceptable range, a "FAIL" message will appear on the QC Results Summary Screen and the "Repeat Failed QC Test(s)" button must be selected.
   1. Verify QC and reagent cassettes are within the expiration date and have been properly stored.
   2. Ensure proper technique is being used to continue with testing as directed by the analyzer.
      a. If Level 1 QC fails, the Clinitek will automatically advance to Level 2 QC before requiring a repeat of Level 1.
      b. If Level 2 QC fails, the QC Results Summary screen will include an additional button to "Repeat Failed QC Test(s)". Press this to repeat the applicable level(s) of QC, as directed by the analyzer.
3. If the repeat falls within the acceptable range and a "PASS" message appears, the QC Summary Screen will summarize this information. Press "Done" to acknowledge successful QC and continue with patient testing.

4. If the QC fails a second time, open new QC vial(s). Repeat test.

5. If the QC fails a third time, open a new box of reagent cassettes. Repeat test.

6. If the QC fails with the new QC solution(s) and reagent cassettes, DO NOT PERFORM ANY PATIENT TESTING.
   a. Contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu. If assistance is required outside business hours, a CORUS message may be sent to "POCT Consult".

---

**Figure 1**

**Figure 2**

**X. PATIENT TEST PROCEDURE**

When both levels of QC have passed and patient testing is available, the "Cassette Test" icon will appear as a large square on the home screen.

A. Prepare for the test:
   1. Ensure the specimen is properly labeled as indicated in Section VI. Specimen Collection and Handling.
   2. Confirm the reagent cassettes are not expired and QC has been tested, as applicable.

B. Program the patient test on the analyzer:
   1. Select the "Cassette Test" icon (see Figure 3).
   2. Scan JHED ID barcode at the prompt for "Operator ID", then select Enter. Alternately, you can manually enter your JHED ID.
   3. Select "Enter New Patient".
   4. Scan the barcode on the patient's label to generate the CSN (10-digit number) on the Enter Patient ID screen.
      a. NOTE: If any identifier other than CSN is used to perform testing, the results will be held as an exception and require intervention to post the results to the patient's chart.
   5. Select "Enter new lot and expiration date" for the cassette.
   6. Scan the barcode on the Cassette package to import the cassette lot number and expiration date.

C. Perform the patient test:
   1. Gently mix the patient specimen by swirling several times.
   2. Open the cassette package and place the cassette on the test table insert.
   3. Remove the specimen container lid.
   4. Touch the "START" icon to start an 8 second countdown. The following steps must be completed during this countdown:
      a. Use the pipette provided with the reagent cassette to draw up a sample for testing:
Subject
Urine Pregnancy Using Clinitest Cassettes on the Clinitek Status+ Connect System

5. The table will retract eight (8) seconds after touching the "START" icon.
6. After the testing process is complete, the table will emerge and the result will display on the screen.
   a. If utilizing wired connectivity, the results will post automatically to the patient's chart.
   b. If a printed copy of the result is desired, press the printer icon.
7. Remove and discard the cassette and pipette in the proper waste container.
8. Select "Done".

XI. REFERENCE RANGES
A. Healthy men and healthy non-pregnant women should not have detectable hCG levels.
B. In pregnant females:
   1. hCG levels of 100 mIU/mL can be reached on the first day of the missed menstrual period.
   2. hCG levels peak about 8-10 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy.
   3. hCG levels rapidly decrease and usually return to normal within days following delivery.
XII. REPORTABLE RANGE
The reportable values of the Clinitest hCG pregnancy test are Negative, Positive, or Borderline.

XIII. RESULTS INTERPRETATION
A. POSITIVE: The instrument will automatically determine if the Test (T) region intensity is at or above the sensitivity of 25 mIU/mL, and confirm the Control (C) and Reference (R) regions meet minimum intensity specifications.
B. BORDERLINE: Result is indeterminate; repeat in 48-72 hours or send an alternate specimen (blood) to the Core Laboratory for quantitative analysis.
C. NEGATIVE: The instrument will automatically determine the Test (T) region is below the test sensitivity of 25 mIU/mL, and confirm the Control (C) and Reference (R) regions meet minimum intensity specifications.
D. INVALID: The analyzer will automatically determine whether a procedural error or test reagent deterioration has occurred by confirming that the Reference (R) and Control (C) regions meet minimum intensity requirements. If not, the operator will be advised to repeat the test and seek technical support if the problem persists.

Note: Negative test results in patients suspected to be pregnant should be retested with a urine sample obtained 48-72 hours later, or by sending a blood sample to the Core Laboratory for quantitative analysis.

XIV. DOCUMENTATION
Patient results will automatically transmit to the electronic medical record, provided no error in data entry has been made, and the computer icon in the top left corner of the screen does not have an "X" over it. If there is an "X" over the computer icon, follow the steps in Procedural Notes and/or Maintenance to troubleshoot and resend results.

The result will display under the "Labs" tab in Epic as "Hcg Ur Point of Care".

XV. LIMITATIONS
A. The test is not intended to detect conditions other than pregnancy. A number of conditions, including trophoblastic disease and certain nontrophoblastic neoplasms, can cause elevated levels of hCG.
B. Clinical diagnosis should not be based solely on a single test result, and should incorporate all available clinical and laboratory data.
C. Because of the lag between conception and the appearance of hCG in urine, to exclude pregnancy with the highest degree of certainty, it is traditional to repeat the test on a fresh sample obtained 2-3 days after obtaining a negative result on the initial sample.
D. Patients on antibody therapy may obtain invalid results due to the presence of interfering antibodies in the medications.
E. The presence of heterophile antibodies or non-specific protein binding may cause false-positive results in sensitive immunoassays. If a qualitative interpretation is inconsistent with the clinical evidence, results should be confirmed using an alternative hCG detection method.

XVI. PROCEDURAL NOTES
A. Do not use anything pointed on the touch screen.
B. Do not push the test table fully into the analyzer, as this may prevent use of the analyzer.
C. Do not move or bump the test table while the analyzer calibrates, as this may cause the calibration to fail.
D. Keep the white calibration bar on the test table clean and do not touch unless performing as needed maintenance. Damage to the calibration bar could affect test results and analyzer functionality. See Section XVIII. Maintenance.
E. Patient test results can be searched by Patient ID (CSN) or by date, or all results can be viewed. See Appendix B for procedural steps.

XVII. MAINTENANCE

Daily: Clean the analyzer exterior.

A. Always keep the exterior of the Clinitek Status+ analyzer and screen clean and free of dust:
   1. Put on gloves.
   2. Hold the on/off button until the analyzer powers down.
   3. Wipe the outside and screen with a damp (not wet) hospital-approved disinfectant wipe.
   4. Wipe the display with a clean cloth dampened with water to remove any residue.
   5. Dry the display with a clean, dry cloth, such as a Kimwipe. Alternately, let air dry before powering the analyzer on.

Weekly: Clean the test table and test table insert.

A. At least weekly and more frequently, as needed:
   1. Put on gloves.
   2. Remove the test table insert (see Figure 6).
   3. Remove the test table by pulling it fully out of the analyzer.
   4. Wet a cotton-tipped stick with water and thoroughly scrub the test table and table insert, except for the white calibration bar (see Figure 7).
      a. If disinfection is necessary, use a hospital-approved disinfectant wipe.
   5. Rinse both sides of the table insert and test table under running water.
   6. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
      a. NOTE: If time allows, air drying is the recommended method.
   7. Examine the white calibration bar on the test table for dirt or discoloration.
      a. If the white calibration bar appears clean and unmarked, insert the test table into the analyzer by pushing it in just over halfway, the re-seat the table insert.
      b. If the bar appears dirty or discolored, clean the calibration bar as described below.

As Needed: Clean the white calibration bar.

A. Check the calibration bar for cleanliness weekly and clean only if needed:
   1. Put on gloves.
   2. Remove the insert from the test table (see Figure 6).
   3. Remove the test table by pulling it fully out of the analyzer.
   4. Examine the white calibration bar on the test table for dirt or discoloration under good lighting (see Figure 7).
      a. NOTE: Take care to not touch the calibration bar. Fingerprints or lint on the bar could cause unreliable test results.
   5. If the white calibration bar appears clean and unmarked, perform the following steps:
      a. Hold the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
      b. Push the test table firmly but slowly just over halfway into the analyzer.
         i. NOTE: Do not push the test table fully into the analyzer, or a jam may occur.
      c. Re-seat the test table insert.
   6. If the white calibration bar is dirty or discolored:
Subject
Urine Pregnancy Using Clinitest Cassettes on the Clinitek Status+ Connect System

a. Wet a cotton-tipped stick or lint-free clot with warm water and gently wipe and clean the calibration bar.
   i. NOTE: Do not scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests.
   ii. NOTE: Do not use solvents of any kind to clean the bar, as this could destroy the white calibration bar.
b. Allow the test table to air dry.
c. Inspect the surface for dust, foreign material, scratches, or scuffs.
d. If you cannot completely clean the calibration bar or if the bar still has marks, contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu.
e. If the calibration bar is free from scratches and foreign material, place the test table into the analyzer as described in Step 5.

XVIII. TROUBLESHOOTING

A. In the event of an error, testing will be stopped immediately, and an Error Code will appear on the analyzer screen. The table below describes the Error Messages, and Action(s) to take when troubleshooting.

B. When recommended Corrective Actions include "Contact the POCT Office":
   1. During business hours (Monday-Friday 7:30-15:00), call 410-955-2645 or email POCTGroup@exchange.johnshopkins.edu.
   2. During off hours, POCT Consult on CORUS may be utilized given a critical issue that cannot wait until the next business day.
   a. NOTE: The JHH Core Lab is the backup for all POCT Clinitek Clinitest hCG testing.

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Error Message</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E02</td>
<td>Failure of calibration data</td>
<td>Contact the POCT Office.</td>
</tr>
<tr>
<td>E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92 or E93</td>
<td>Failure of computer software</td>
<td>Contact the POCT Office.</td>
</tr>
<tr>
<td>Error Code</td>
<td>Description</td>
<td>Instructions</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| E10 or E48 | Loss of test results                 | 1. Press the on/off button to power down the analyzer; leave off for at least 30 seconds.
|            |                                      | 2. Press the on/off button to restart the analyzer.
|            |                                      | 3. Repeat the test.                                                         |
| E11        | Failure of test table                | 1. Move the test table in or out of the analyzer slightly to reposition, but no more than halfway.
|            |                                      | 2. If the error remains, with the analyzer powered on, pull the power cord from the back of the analyzer, and leave it powered off for at least 30 seconds.
|            |                                      | 3. Plug the cord back in, then press the on/off button to restart the analyzer.
|            |                                      | 4. If the error remains with the test table in place, contact the POCT Office. |
| E12        | Failure of LED                       | Contact the POCT Office.                                                   |
| E20        | Failure of clock                     | Contact the POCT Office.                                                  |
| E24        | No printer paper                     | Replace the printer paper by selecting Error Report to view the instructions or by opening the printer paper compartment cover to view the instructions inside. |
| E25, E64 or E65 | Failure of automatic calibration | Clean the calibration bar. If the error remains after cleaning, contact the POCT Office. |
| E28        | Printer error                        | 1. Lift the printer cover.
|            |                                      | 2. Push the gray paper holding arm back into position.                     |
| E52        | Invalid barcode                      | Repeat the test using the correct Siemens cassette.                        |
| E53        | Strip Test selected but cassette detected | Repeat the test using the cassette test function.                              |
| E54        | Cassette Test selected but strip detected | Repeat the test using the strip test function.                             |
| E57        | Missing strip or cassette            | Repeat the test and ensure that you correctly position the strip or cassette on the test table. |
| E62        | Light Ingress                       | Too much light is reflecting on the analyzer. Move the analyzer to a location with lower lighting. |
| E67 or E68 | Sampling Error                       | Sample flow issue detected. One or more test indicator lines are missing or indiscernible, or insufficient or excess sample was applied to the cassette. Ensure correct filling of the pipette, then dispense the sample into the well of the cassette. If the error occurs with a highly colored or visibly bloody or viscous sample, collect a fresh sample and repeat the test. |
B. Troubleshooting the Analyzer Operation given symbols present on the Select Ready screen:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>No Printer Paper</td>
<td>Displays on the Print Help button on the Select Ready screen, indicating that the printer is out of paper. An advisory message also displays. Replace the empty paper or label roll with a new one, following the instructions under the printer paper compartment cover.</td>
</tr>
</tbody>
</table>
| ![Icon](image) | No Connector              | Indicates that the analyzer is not connected to the connector.  
  1. Disconnect the double-sided black connector, then blow into it to remove any dust accumulated. Invert the positioning of the connector when reconnecting.  
  2. If the issue persists more than 2 minutes after completing step 1, contact the POCT Office. |
| ![Icon](image) | No Remote Connection      | Indicates that the wired connection between the analyzer and the server does not exist.  
  1. Press and hold the on/off button to power down the analyzer.  
  2. Unplug the power cord from the analyzer for 30 seconds.  
  3. Plug the power cord back into the analyzer, then power on the analyzer.  
  4. If problem persists more than 2 minutes after completing steps 1-3, contact the POCT Office. |
XIX. DOWNTIME

Instrument Downtime:

A. When the Clinitek Status+ Connect system cannot be used for patient testing due to QC, calibration, or instrument failure and all troubleshooting steps have been performed, contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu during business hours (Monday-Friday 7:30-15:00).
   1. During off-hours, contact the POCT Office for all urgent issues that cannot wait until the next business day by sending a CORUS message to "POCT Consult".
   2. If the absence of a back-up analyzer, send patient specimens to the Core Laboratory.

Epic and/or Telcor Downtime:

A. The Clinitek Status+ Connect System may still be used for QC and patient testing, but results will not automatically cross.
   1. NOTE: Do not manually document results on patient charts unless directed to do so by the POCT Office.

B. Once connectivity is re-established and the computer icon at the top left of the display screen shows a connection results will begin posting to patient charts automatically. If results are missing, contact the POCT Office for additional guidance and refer to Appendix B for steps to Resend Results as needed.

XX. OPERATOR TRAINING

A. Testing may be performed only by testing personnel who have been trained by a Point-of-Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file and a copy sent to the Point-of-Care Testing office.

B. Initial Training must include the following:
   1. Review and acknowledge the SOP.
   2. Successful performance of both levels of liquid quality control associated with the testing personnel's JHED ID.
   3. Completion of the initial competency assessment checklist (see Appendix C), to be kept in the employee's personnel file and a copy sent to the POCT Office.
   4. Passing score on the quiz following the MyLearning module.

C. All Initial Training and Competency requirements must be completed prior to performing any patient testing.

XXI. OPERATOR COMPETENCY

In order to maintain ongoing competency and not lose access to the analyzer, all testing personnel must successfully complete both levels of controls and the MyLearning module at least once a year.

The POCT Office competency cycle follows the fiscal year. Testing personnel who do not complete requirements during a given competency cycle will require re-completion of Initial Training and Competency prior to being regranted access to the analyzer.

XXII. REFERENCES


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XXIII. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Clarke</td>
<td>07/14/2022</td>
</tr>
<tr>
<td>Andrew Satin</td>
<td>07/19/2022</td>
</tr>
<tr>
<td>Rebecca Stone</td>
<td>07/25/2022</td>
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