Q&A column

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Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

Q. Should peritoneal dialysis fluid collected directly from a patient be considered peritoneal fluid or peritoneal dialysate fluid? A clinician at my institution placed an order for peritoneal dialysate fluid because the fluid was to be collected from the patient, not from the bag.

A.May 2022—The peritoneal cavity refers to a potential space, lined by a single layer of mesothelial cells, within the abdomen. It consists of the parietal peritoneum, which covers the abdominal wall and the diaphragm, and the visceral peritoneum, which covers such intra-abdominal organs as the liver, spleen, stomach, and intestines. With a surface area of 1 to 2 m^2, the peritoneal cavity is considered the largest serosal cavity in the body.[1] Under normal conditions, there is a small amount of lubricating fluid within the space that allows organs to move freely within the cavity.

Ascites is the accumulation of fluid within the peritoneal cavity due to pathological causes and most often results from liver cirrhosis. Other causes include malignancy, heart failure, and tuberculosis.[2] The clinical features of ascites include abdominal distension, abdominal discomfort, dyspnea, and weight gain. The principle physical exam finding is flank dullness. Performing maneuvers such as the fluid wave test and the shifting dullness test can increase the diagnostic accuracy of the physical exam. Imaging modalities, such as ultrasound, can be used to confirm ascites.

Once ascites has been diagnosed, the next step is usually to determine the underlying cause. This process frequently involves obtaining a sample of the fluid for laboratory analysis. Cell counts, special stains, adenosine deaminase activity tests, and cultures may be ordered in the infectious disease workup, whereas cytologic examination and tumor marker assays (e.g. CA125 and CEA) can be useful in the malignancy workup.[3]

Portal hypertension is a manifestation of liver cirrhosis, and the serum-ascites albumin gradient, or SAAG, is perhaps the most widely employed test when portal hypertension is suspected. The SAAG is calculated by subtracting the ascitic fluid albumin value from the serum albumin value obtained on the same day. Studies have shown that a SAAG result of ≥1.1 g/dL can identify portal hypertension 96.7 percent of the time.[4]

A nonpathologic cause of excess fluid in the abdomen is peritoneal dialysis. Patients with end-stage renal disease who meet certain requirements and prefer less disruption to their daily activities may choose peritoneal dialysis over hemodialysis. There are two types of peritoneal dialysis: continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD).

With CAPD, dialysis fluid is instilled or drained manually at various times throughout the day. Automated peritoneal dialysis involves a device that performs these fluid exchanges typically while a patient sleeps at night.[5] The dialysis solution, also known as dialysate, contains osmotic agents (e.g. glucose polymers), buffers (e.g. lactate and bicarbonate), and electrolytes (e.g. sodium, potassium, and magnesium). The dialysate is infused into the peritoneal cavity and allowed to dwell for a prescribed period of time, during which uremic toxins are eliminated from the circulatory system through the peritoneal membrane.

There are several ways to evaluate the efficacy of peritoneal dialysis during therapy. One recommended metric is

the Kt/V value for urea, in which K is the peritoneal urea clearance, t is time, and V is the volume of distribution of urea, which is approximately equal to the patient's total body water volume.[6] Formulas for calculating Kt/V range from simple ones requiring only pre- and post-blood urea nitrogen (BUN) to much more complex, full kinetic models.

The peritoneal equilibration test (PET), introduced in 1987, is another important tool for evaluating peritoneal membrane transport function because it takes into account the dialysate-to-plasma ratio of creatinine and glucose, ultrafiltration volume, and samples taken at multiple time points.[7,8] Various groups have advocated for modifying the traditional PET.[9,10]

Returning to the reader's question, one should consider, for example, that a glucose measurement using fluid drawn from the peritoneal cavity would have different implications in evaluating bacterial peritonitis than it would in a routine peritoneal equilibration test. Even for patients with underlying liver cirrhosis and ascites who are undergoing peritoneal dialysis, the timing of sample collection influences whether the fluid is composed primarily of ascites or dialysate. Similarly, catheterized urine has relevant differences compared to bladder washing fluid, even though they are obtained from essentially the same anatomic location. Therefore, how the laboratory reports testing results can materially influence how the data are ultimately being interpreted. Without a notation or disclaimer, a result otherwise listed as peritoneal fluid in the medical record would likely be assumed to have been ascites fluid. In the scenario presented by the reader, documenting the fluid sample based on its primary composition or type (i.e. dialysate) instead of by its anatomic source provides key clinical context to the patient's care team. However, if possible, documenting the fluid source and fluid type is optimal.

Finally, a laboratory should review potential regulatory compliance issues in relation to body fluid testing. Because few manufacturers offer commercial FDA-cleared body fluid tests, laboratories must often develop their own extensive validation methods to provide testing for the variety of body fluids they receive.[11] As laboratorians, we must be cognizant of the potential for matrix interference when we evaluate requests for body fluid testing or alternative matrices and ensure that we have completed the necessary due diligence to demonstrate analytical validity.

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Q. What types of materials (for example, QC materials, patient samples, or both) can be used to check new reagent lots on my chemistry analyzer? We have three chemistry analyzers of the same model. Do we need to perform reagent lot studies on all three?

A.Your question relates to the CAP checklist COM.30450 New Reagent Lot and Shipment Confirmation of Acceptability—Nonwaived Tests. The checklist says, "New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service."

The note in the checklist requirement indicates there are several materials that can be used, but patient samples are preferred. The CAP does not require that you use both patient samples and quality control material. It is up to your laboratory director to determine which material to use and the extent of the testing.

For quantitative testing, the checklist note provides the following list of suitable reference materials for checking new reagent lots and shipments:

- Patient specimens tested on a previous lot.
- Reference materials or QC products provided by the method manufacturer with method-specific and reagent lot-specific target values.
- Proficiency testing materials with peer group-established means.
- QC materials with peer group-established means based on interlaboratory

comparison that is method specific and includes data from at least 10 laboratories.

- Third-party general-purpose reference materials if commutable with patient specimens for the method (per package insert or method manufacturer).
- QC material in use with the current reagent lot to check a new shipment of the same reagent lot. (There should be no change in potential matrix interactions with use of the same lot number of reagent and QC material.)

You need to perform this new reagent lot-to-lot verification using only one of your three analyzers. A separate checklist requirement (COM.04250) says, "If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results."

Clinical and Laboratory Standards Institute. EP26-A: User Evaluation of Between-Reagent Lot Variation; Approved Guideline, 1st ed.; 2013.

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