Q&A column, 11/16

Editor: Frederick L. Kiechle, MD, PhD

Dr. Kiechle is medical director of clinical pathology, Memorial Healthcare, Hollywood, Fla. Use the reader service card to submit your inquiries, or address them to Sherrie Rice, CAP TODAY, 325 Waukegan Road, Northfield, IL 60093; srice@cap.org. Those questions that are of general interest will be answered.

Submit a Question

Q. As originally described, there are technically five Gleason patterns: 1, 2, 3, 4, 5. However, since patterns 1 and 2 are never used, there are no Gleason scores 1 + 1 = 2, 1 + 2 = 3, 2 + 1 = 3, 2 + 2 = 4, 2 + 3 = 5, and 3 + 2 = 5. Why is this? Isn't this an alteration of Gleason's original classification concept? Furthermore, there are cases in which a biopsy may contain a few glands that are diagnostic of carcinoma but insufficient to assign an accurate Gleason score. Would it simply be best to make a descriptive comment to that effect?

A. The Gleason grading system for prostate cancer has undergone significant changes since its inception in 1966. The most significant changes were codified and documented in two consensus opinion articles published by the International Society of Urological Pathology. The most important change is perhaps the strict definition of each pattern. Due to its misleading clinical implications, a Gleason score of 1+1=2 should not be rendered, regardless of the specimen type. A Gleason score of 2–4 should rarely be rendered in needle biopsies, if ever. The major limitation of diagnosing Gleason patterns 1 and 2 on needle biopsy is that one cannot see the entire edge of the lesion to determine if it is circumscribed. They may be used rarely in transurethral resection (TURP) and radical prostatectomy (RP) specimens. Therefore, from a practical standpoint, a Gleason pattern in contemporary practice starts at 3, and a Gleason score starts at 6 in prostate biopsy specimens and most TURP and RP specimens.

Since a Gleason score is used by clinicians to manage prostate cancer patients, it should be provided for every cancer case even if the cancer focus is minute. In a majority of cases, a minute focus of cancer is graded as 3+3=6. Clinicians will of course also take into consideration the size of the cancer focus when determining a treatment plan.

1. Epstein JI, Allsbrook WC Jr, Amin MB, Egevad LL; ISUP Grading Committee. The 2005 International Society of Urological Pathology (ISUP) consensus conference on Gleason grading of prostatic carcinoma. *Am J Surg Pathol.* 2005;29(9):1228–1242.
2. Epstein JI, Egevad L, Amin MB, et al.; the Grading Committee. The 2014 International Society of Urological Pathology (ISUP) consensus conference on Gleason grading of prostatic carcinoma: definition of grading patterns and proposal for a new grading system. *Am J Surg Pathol.* 2016;40(2):244–252.
3. Shah RB, Zhou M. Recent advances in prostate cancer pathology: Gleason grading and beyond. *Pathol Int.* 2016;66(5):260–272.

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Q. I worked in multiple hospitals where the laboratory and respiratory services were under the same CLIA number. Comparability studies were performed between the blood gas hemoglobin and the hematology analyzer hemoglobin results. Is this required under CLIA? Technically the test is different because one is arterial (ABG) and one is venous (CBC).

A. The intent of the CLIA regulation and CAP checklist requirement COM.04250 is to ensure clinical comparability of results. Blood gas hemoglobin and central laboratory hemoglobin results are often clinically compared and sometimes used serially to decide if the hemoglobin is stable. If both instruments are reporting out hemoglobin results under the same CLIA number, the hemoglobin results must be compared at least twice a year to define the relationship between test results using the different methods.

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Q. I have conflicting results for correction of lipemia and bilirubinemia. Please explain the right way to correct CBC parameters for lipemia and bilirubinemia.

A. Increased sample turbidity due to lipemia or hyperbilirubinemia (icterus) can falsely elevate hemoglobin, which is measured by photometric methods but is not likely to affect impedance-based counts of red blood cells, white blood cells, or platelets. False elevation of the hemoglobin value results in poorly correlated hemoglobin and hematocrit values and in erroneously calculated (and falsely elevated) mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC) values, which should flag a sample for further investigation.

Two approaches have been suggested for correcting for lipemia and hyperbilirubinemia: the saline replacement method and the plasma hemoglobin blank procedure.

Saline replacement involves removing the plasma from the red blood cells and re-suspending the red blood cells in an equal volume of saline. After mixing the sample well, running the saline-replaced sample on the instrument should yield a valid hemoglobin value.

The plasma hemoglobin blank method involves removing an aliquot of plasma from the patient sample and running the plasma sample on the hematology instrument to determine the “plasma hemoglobin” value attributable to interfering substances.1 This value is used in the following formula to derive the corrected hemoglobin value:

$$\text{Corrected hemoglobin} = \text{original hemoglobin} - [(1 - \text{hematocrit}) \times \text{plasma hemoglobin}$$

The corrected hemoglobin value can then be used to calculate accurate MCH and MCHC values.

An alternative approach that some laboratories use is to report only the result of a spun hematocrit and not to report a hemoglobin value. A code may be entered for MCH and MCHC indicating that results are not available due to the lack of a valid hemoglobin result.

1. Cornbleet J. Spurious results from automated hematology cell counters. *Lab Med.* 1983;14(8):509–514.

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Q. A member of my laboratory staff is suspected of using drugs of abuse, and he underwent drug screening as a result. When the reference laboratory we used for this returned the results, I discussed them with my laboratory manager. Later, my manager told me that someone in human resources said that I, as medical director and contracted (full-time) physician, am not privy to this employee's test results because of HIPAA concerns. Is this true? If so, how am I to make an informed decision about the employee's fitness for work?

A. The staff member's drug test results are protected health information under the Health Insurance Portability and Accountability Act of 1996. However, if the employee consented to be tested as a condition of employment and such authorization is in the employee's record, you are permitted to see the results and to act on them. If there is no authorization, you are not permitted to do so. In fact, if the employee did not consent as a condition of employment, no drug testing should have been done. The pertinent regulation is 45CFR164.508(a).

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