| **Required/ Recommended** | **Element name** | **Values** | **Commentary** | **Implementation notes** |
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| Recommended | CLINICAL INFORMATION | Not provided  OR  Multi selection value list (select all that apply): •Previous history of prostate cancer (including the Gleason grade and score of previous specimens if known) • Previous biopsy, specify date and where performed • Previous therapy, specify  • Other, specify | It is the responsibility of the clinician requesting the pathological examination of a specimen to provide information that will have an impact on the diagnostic process or affect its interpretation. The use of a standard pathology requisition/request form including a checklist of important clinical information is strongly encouraged to help ensure that relevant clinical data is provided by the clinicians with the specimen. Information about prior biopsies or treatment aids interpretation of the microscopic findings and accurate pathological diagnosis, while knowledge of the number of needle cores taken from each site aids pathological assessment of the number of involved cores. Radiation and/or endocrine therapy for prostate cancer have a profound effect on the morphology of both the cancer and the benign prostatic tissue. For this reason, information about any previous therapy is important for the accurate assessment of needle core biopsies. Following irradiation, benign acinar epithelium shows nuclear enlargement and nucleolar prominence, 1 while basal cells may show cytological atypia, nuclear enlargement and nuclear smudging. 2 There may also be increased stromal fibrosis, which may resemble tumour-induced desmoplasia. These changes may persist for a considerable period, having been reported up to 72 months after treatment, and are more pronounced in patients who have undergone brachytherapy compared to those who have received external beam radiation therapy.2,3 It is important to document any previous radiotherapy to help the pathologist to interpret changes accurately. Radiation may be associated with apparent upgrading of prostate cancer in prostatectomy specimens. 4 Likewise, neoadjuvant androgen deprivation therapy (ADT) may induce morphological changes in both prostate cancer and benign tissue. Androgen blockade induces basal cell hyperplasia and cytoplasmic vacuolation in benign prostatic tissue, although this is unlikely to be confused with malignancy. 5 More significantly from a diagnostic point of view, neoadjuvant ADT may increase the risk of overlooking acinar adenocarcinoma on low power microscopic examination due to collapse of glandular lumina, cytoplasmic pallor and shrinking of nuclei.6-8 The effect of androgen blockage on prostate cancer is variable and an apparent upgrading of the cancer has been reported in a number of studies.4,5 Hence, it has been suggested that in biopsies undertaken following either radiotherapy or androgen deprivation therapy, tumours that show significant treatment effect should not be graded.9 The Gleason grade and score of prostate cancer in any previously submitted specimen should also be provided by the clinician as this allows assessment of any progression of the tumour towards a higher grade/more undifferentiated state, which itself may be of prognostic significance. If the patient is on active surveillance this information should also be included.  References  1 Cheng L, Cheville JC and Bostwick DG (1999). Diagnosis of prostate cancer in needle biopsies after radiation therapy. Am J Surg Pathol 23(10):1173–1183.  2 Magi-Galluzzi C, Sanderson HBS and Epstein JI (2003). Atypia in non-neoplastic prostate glands after radiotherapy for prostate cancer: duration of atypia and relation to type of radiotherapy. Am J Surg Pathol 27:206–212.  3 Herr HW and Whitmore WF, Jr (1982). Significance of prostatic biopsies after radiation therapy for carcinoma of the prostate. Prostate 3(4):339–350.  4 Grignon DJ and Sakr WA (1995). Histologic effects of radiation therapy and total androgen blockage on prostate cancer. Cancer 75:1837–1841.  5 Vailancourt L, Ttu B, Fradet Y, Dupont A, Gomez J, Cusan L, Suburu ER, Diamond P, Candas B and Labrie F (1996). Effect of neoadjuvant endocrine therapy (combined androgen blockade) on normal prostate and prostatic carcinoma. A randomized study. Am J Surg Pathol 20(1):86- 93.  6 Montironi R, Magi-Galluzzi C, Muzzonigro G, Prete E, Polito M and Fabris G (1994). Effects of combination endocrine treatment on normal prostate, prostatic intraepithelial neoplasia, and prostatic adenocarcinoma. J Clin Pathol 47(10):906-913.  7 Civantos F, Marcial MA, Banks ER, Ho CK, Speights VO, Drew PA, Murphy WM and Soloway MS (1995). Pathology of androgen deprivation therapy in prostate carcinoma. A comparative study of 173 patients. Cancer 75(7):1634-1641.  8 Bostwick DG and Meiers I (2007). Diagnosis of prostatic carcinoma after therapy. Arch Pathol Lab Med 131(3):360-371.  9 Epstein JI and Yang XJ (2002). Benign and malignant prostate following treatment. In: Prostate Biopsy Interpretation, Lippincott Williams and Wilkins, Philadelphia, Pennsylvania, 209–225. |  |
| Recommended | PRE-BIOPSY SERUM PSA | Numeric:  • \_\_\_ ng/mL | The clinician requesting the pathological examination should provide information on the pre-biopsy serum prostate-specific antigen (PSA) level. The use of a standard pathology requisition/request form including a checklist of important clinical information is strongly encouraged to help ensure that important clinical data is provided by the clinicians with the specimen. Despite criticisms about the utility of PSA-based prostate cancer screening, most prostate cancers are detected in asymptomatic men on the basis of PSA testing. Although PSA levels provide some indication of the likelihood of discovering cancer within a biopsy of the prostate, a diagnosis of malignancy should be based on histological findings and should not be influenced by PSA levels. In addition, serum PSA is a key parameter in some nomograms widely used to pre-operatively predict the American Joint Committee on Cancer (AJCC)/Union of International Cancer Control (UICC) pathological T category of prostate cancer or the risk of recurrence following radical prostatectomy and to guide clinical decision making with respect to disease management. 1 If the patient is on 5-alpha-reductase inhibitor medications, such as finasteride or dutasteride, this should be recorded as it may lower serum PSA levels and affect interpretation of serum PSA values for detecting prostate cancer.2-4  References  1 Eifler JB, Feng Z, Lin BM, Partin MT, Humphreys EB, Han M, Epstein JI, Walsh PC, Trock BJ and Partin AW (2013). An updated prostate cancer staging nomogram (Partin tables) based on cases from 2006 to 2011. BJU Int 111(1):22-29.  2 Guess HA, Gormley GJ, Stoner E and Oesterling JE (1996). The effect of finasteride on prostate specific antigen: review of available data. J Urol 155(1):3-9.  3 Oesterling JE, Roy J, Agha A, Shown T, Krarup T, Johansen T, Lagerkvist M, Gormley G, Bach M and Waldstreicher J (1997). Biologic variability of prostate-specific antigen and its usefulness as a marker for prostate cancer: effects of finasteride. The Finasteride PSA Study Group. Urology 50(1):13-18.  4 Marberger M, Freedland SJ, Andriole GL, Emberton M, Pettaway C, Montorsi F, Teloken C, Rittmaster RS, Somerville MC and Castro R (2012). Usefulness of prostate-specific antigen (PSA) rise as a marker of prostate cancer in men treated with dutasteride: lessons from the REDUCE study. BJU Int 109(8):1162-1169. |  |
| Required | SPECIMEN SUBMITTED | Numeric and Text:  \_\_ Specimen/container identification  \_\_ Location from which taken ( if specified)  \_\_ Total number of cores  \_\_ Length of core(s) | Information on specimens submitted for histopathological examination, including location, number of needle cores and length of cores, is regarded as an integral and essential part of a pathology report.1 The length of the cores should be measured in the wet specimen before tissue processing and paraffin embedding. Preferably there should be only 1 needle core in each specimen jar. However, if 2 or more needle cores are submitted in one container and there is some fragmentation, it may not be possible to reliably determine the number of involved cores. In this situation the urologist should state on the pathology request/requisition form how many cores were submitted in each jar to avoid counting fragments of the one core as separate cores (particularly with cores <6 mm long) and providing misleading information on tumour extent.2 Where more than 5 cores are submitted in a specimen jar, e.g. with saturation/template biopsies, a range may be submitted for length of the cores rather than measuring each one individually.  References  1 ICCR (International Collaboration on Cancer Reporting) (2017). Guidelines for the development of ICCR datasets. Available from: http://www.iccr-cancer.org/datasets/ dataset-development (Accessed 1st March 2017).  2 Amin MB, Lin DW, Gore JL, Srigley JR, Samaratunga H, Egevad L, Rubin M, Nacey J, Carter HB, Klotz L, Sandler H, Zietman AL, Holden S, Montironi R, Humphrey PA, Evans AJ, Epstein JI, Delahunt B, McKenney JK, Berney D, Wheeler TM, Chinnaiyan AM, True L, Knudsen B and Hammond ME (2014). The critical role of the pathologist in determining eligibility for active surveillance as a management option in patients with prostate cancer: consensus statement with recommendations supported by the College of American Pathologists, International Society of Urological Pathology, Association of Directors of Anatomic and Surgical Pathology, the New Zealand Society of Pathologists, and the Prostate Cancer Foundation. Arch Pathol Lab Med 138(10):1387-1405. |  |
| Recommended | CLINICAL STAGE | Text | The clinician requesting the pathological examination should provide information on the clinical stage. The use of a standard pathology requisition/request form including a checklist of important clinical information is strongly encouraged to help ensure that important clinical data is provided by the clinicians with the specimen. Along with pre-biopsy serum prostate-specific antigen (PSA), clinical stage is a vital parameter in some nomograms widely used to pre-operatively predict the pathological T category of prostate cancer and to guide clinical decision making with respect to disease management. 1  References  1 Eifler JB, Feng Z, Lin BM, Partin MT, Humphreys EB, Han M, Epstein JI, Walsh PC, Trock BJ and Partin AW (2013). An updated prostate cancer staging nomogram (Partin tables) based on cases from 2006 to 2011. BJU Int 111(1):22-29. |  |
| Recommended | BLOCK IDENTIFICATION KEY | Text | The origin/designation of all tissue blocks should be recorded and it is preferable to document this information in the final pathology report. If this information is not included in the final pathology report, it should be available on the laboratory computer system and relayed to the reviewing pathologist.1 Specifically for needle core biopsy cases, this information may be helpful in interpreting specimens where the urologist has submitted more than one needle core per specimen container. Recording the origin/designation of tissue blocks also facilitates retrieval of blocks, for example for further immunohistochemical or molecular analysis, research studies or clinical trials.  References  1 ICCR (International Collaboration on Cancer Reporting) (2017). Guidelines for the development of ICCR datasets. Available from: http://www.iccr-cancer.org/datasets/ dataset-development (Accessed 1st March 2017). | List overleaf or separately with an indication of the nature and origin of all tissue blocks. |