**qTrucheck Pre-Test Counselling Sheet**

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| **Topic** | **Details** | | |
| **Test information** | Trucheck is a blood test that can detect more than 70 types of early stage cancer within the asymptomatic population.  In the UK there are 1000 new cases of cancer diagnosed per day, with 48% of those cases being caught in the later stages (3&4), where interventions are more aggressive and patient outcomes are worse.  Trucheck has been developed to detect cancer early, when management of the disease is more effective and in many cases curative. | | |
| Trucheck uses Circulating Tumour Cells (CTCs) and their clusters (C-ETACs) to assess active cancer status.  As a biomarker, CTCs & C-ETACs have been established as a hallmark of cancer through extensive clinical validations involving more than 40,000 participants.  These CTCs and C-ETACs are present in the blood of almost all cancer patients and are undetectable even in healthy individuals. | | |
| **Intended use** | Trucheck is intended to be used as a cancer screening tool in the asymptomatic general population with only age associated risk.  The only exception to this is for Trucheck prostate, which can be used following a raised PSA test of 3ng/mL or higher. | | |
| **Possible test outcomes** | Positive for malignancy | Active malignancy has confirmed by Trucheck.  Additional follow up procedures will be required to confirm diagnosis. | Join existing care pathway:  1) Imaging  2) Tissue biopsy  3) Endoscopy  4) Other diagnostic procedure |
| Negative for malignancy | There is no active malignancy present in the body and the patients one year risk of developing cancer is very low. | Enjoy the peace of mind given by the negative test result. It is recommended that Trucheck be repeated annually to manage cancer risk |
| Equivocal | Result does not confirm or rule out active malignancy | Advised to repeat Trucheck in 8 to 12 weeks. (Free of charge) |
| Indeterminate | Type of malignancy, or organ of origin could not be determined. | Recollection of sample is required to determine result. (Free of charge) |
| **Benefits** | Psychosocial benefits | Negative results give peace of mind to individuals regarding their active cancer status. | |
| Fast & effective follow up | Positive results that give an indication of tissue and organ of origin, allow for fast tracked and targeted follow up using imaging, biopsy, or other methods to confirm diagnosis.  This means undergoing minimal effective exposure to medical procedures and risks such as radiation. | |
| **Risks** | Psychosocial implications | Anxiety may arise for individuals and their families as they await results, or if they fall into the “Equivocal” or “Indeterminate” result categories.  Although highly unlikely, it is also possible that additional psychological and behavioural consequences may occur from receiving a false negative or false positive result. | |
| **Limitations** | Blood cancers | Trucheck cannot detect blood cancers, because CTCs and C-ETACs are only associated with solid organ malignancies. | |
| Sensitivity | This is the ability of the test to correctly identify patients with cancer.  Trucheck has a specificity of 99% - meaning that for every 100 patients tested who have cancer, it will correctly identify 99 of those patients. Resulting in a 1% false negative rate | |
| Specificity | The ability of the test to correctly identify people without cancer.  Trucheck has a specificity of 99% - meaning that for every 100 people tested, that do not have cancer, Trucheck will correctly identify 99 of these individuals. Resulting in a 1% false positive rate. | |
| **Considerations** | Cost | Trucheck is not currently covered by healthcare insurance in the UK and the costs involved to access the test are privately funded by the individual.  Test price is £950 - this is excluding the costs for pre and post medical consultations.  Following a positive result patients will need to self-pay for additional diagnostic procedures prior to diagnosis. | |