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SPECIAL INTEREST GROUP OF THE SOUTH AFRICAN MEDICAL ASSOCIATION

NATIONAL PATHOLOGY GROUP CODING GUIDELINE

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Version 5
December 2013

PREAMBLE:

The guidelines are intended to be used for purposes of including consistent codes for services rendered to patients. Accordingly, all profiles, individual tests and billing codes are reviewed and updated.

The Guidelines also reflect the current best practice for the matters dealt with in the Guidelines for pathology treatments and testing. Therefore, every effort has been made to align the Guidelines with both international and local best practice, which is a principal recognised in terms of legislation pertaining to medical schemes, more particularly, the definition of the term “evidence-based medicine” in Regulation 15 of the General Regulations (GNR 1262, dated 20 October 1999) to the Medical Schemes Act No. 131 of 1998, as amended, being “the conscientious, explicit and judicious use of current best evidence in making decisions about the care beneficiary whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research”. In addition, the Guidelines reflect international learning obtained by pathologists from international sources, general articles, academy texts and practice experience.

Guidelines are intended to be used for the coding of pathology services by our members. The Guidelines are not rigid, nor are they to be applied all of the time.

Pathologists are the bridge between the clinician and the laboratory. They are specialist consultants. The use of their expertise should be encouraged by their clinical colleagues to ensure the most appropriate service for and outcome to patients.

The Guidelines will be periodically modified by decision of the executive committee based on expert advice. The contents of this document supersede and take precedence over any previous guidelines published by the NPG.

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infringement and may, in certain circumstances, expose the transgressor to criminal prosecution.

The profiles referred to in this document have been determined by pathologists with reference to local healthcare conditions. The profiles used in the Guideline are recommendations only but are based on good pathology practice. Any acts conducted by any pathologist beyond the recommended profile should be conducted only with the consent of the patient and patient's attending healthcare provider.

TJAART ERASMUS
PRESIDENT

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REQUEST FORM

The National Pathology group discourages the use of hand written request forms as such forms lead to transcription errors and the misreading of test requests. Therefore, in the event that a request for a test or profile of tests is hand written and where more than one profile is available for testing (i.e. liver function, cardiac or lipid profiles), and where there is no stipulation in the request as to the exact profile requested, the full profile will be performed in order to ensure that a complete investigation of the biochemical or other parameters is capable of being assessed.

Layout Profiles or Group Tests:

Both profiles and their constituent tests are to be listed on request forms or folders. It must be possible for a referring healthcare provider to request tests, which form part of recognised profiles, as individual items.

Profiles should be listed first in an identifiable category or disease-related group

Profiles or group tests: In order to avoid a proliferation of medically questionable testing profiles and to avoid the use of unacceptable or unreasonable profiles, it is recommended that only profiles accepted by the National Pathology Group may appear on request forms.

The profiles should appear as indicated in the Guidelines and should contain only the tests as listed.

The laboratory should make the contents of profiles known to the requesting healthcare provider.

Specific and Generic request forms:

The request forms should comply with the Guidelines. Request forms should not include unreasonable or medically questionable procedures or tests where a procedure or test is used or recommended without evidence to support the acceptability of such a test amongst the profession. The request forms must comply with good practice and industry norms in order to ensure that costs are contained, where possible. However, deviations from a request form may be permitted if appropriate to any particular treatment regime recommended by a healthcare practitioner to a patient and for which appropriate consent has been obtained from the patient pursuant to the provisions of South African law and the ethical code applicable to the healthcare practitioner concerned. To this end, request forms should make provision for a space in which a particular healthcare practitioner may add or note particular additional testing in so far as the healthcare practitioner is of the view that such testing is appropriate for that patient in the particular circumstances and the testing occurs with the patient's consent.

ADDITIONAL TESTING:

In line with specialist medical practice in other medical disciplines, the interaction of the specialist pathologist in a laboratory testing may result in additional testing. Such additional testing will take place when abnormal results are found that require further investigation in order to elucidate the diagnostic problem. Laboratories must maintain an audit trail when additional tests are conducted either by motivating and evidencing why an additional test

was conducted or confirming in writing that a referring healthcare provider instructed that such additional tests be conducted.

CODING:

Members of the NPG must ensure that appropriate descriptor codes is used for each investigation or test performed in their laboratories.

LABORATORY REQUEST NUMBERS:

In order to provide accurate healthcare information by a laboratory to a healthcare provider, each request for a patient must be allocated a separate laboratory request number. Laboratory request number must be allocated to the request by the laboratory performing the test. Multiple patient incidents should not be allocated one laboratory request number. A code may be used more than once on a laboratory request number as some codes are not specific due to the fact that there is often an absence of specific codes in South Africa and will relate to tests using the same methodology. Such generic codes may occur more than once in a claim but must be accompanied by the appropriate descriptions for each test performed. This will include histology and cytology where multiple specimens may be examined under the same laboratory accession number.

UNBUNDLING:

Unbundling of group tests such as full-blood count, urea and electrolyte codes and blood gas analysis is unacceptable. Where several tests are included in one code, such tests cannot be split into their component parts on a bill.

However, it may happen that components of a group test, such as Hb & Total WBC may be requested by a healthcare provider as separate tests. Accordingly, as only these tests will be conducted only those tests may be charged for and this will not constitute unbundling. In order to ensure that costs are contained, the total of the individual tests must remain less than that of the group test.

CONSULTATION FEES:

Where specific consultation, examination or monitoring of a patient is required and is performed by a pathologist, consultation fees may be charged as agreed between the pathologist and the patient.

INTELLECTUAL PROPERTY:

The Guidelines are the specific intellectual property of the NPG, who will retain the right to amend and review the content of the Guidelines from time to time.

CHEMISTRY

GENERAL GUIDELINES:

- 1 Faecal Occult blood (4351) and Monoclonal Occult blood (4352) could be requested together but in a very low percentage of cases < 5%. Should not be on one request line as in order to ensure clarity and certainly in respect of tests requested.
- 2 HbA1c and Fructosamine (4063) could be requested together but in a very low percentage of cases < 5%. Should not be on one request line.
- 3 Serum Creatinine (4032) could be used together with serum – urea (4151) in a very high percentage of cases > 90%.
- 4 Not more than one tumour marker should appear on one line on request form.
- 5 Amylase and Lipase should not appear on one line on the request form.
- 6 Free PSA should be performed where the total PSA result is between 2.5 and 10 ng/ml.
- 7 The 2nd trimester Downs screen should be described using code 4552 at 38.22 units.
- 8 **Complement:** There are numerous complement components which the laboratories may measure e.g. C3, C4, C5, C6 etc. Prior to the early 1990's all components were measured by the radial immunodiffusion method (code 3963, which has a similar unit value to code 3971 = immunodiffusion test: per antigen) this remains the only method currently available to measure, albeit inaccurately, C5 and C6 levels.

During the 1990's more accurate nephelometric and immunoturbidometric methods became available to measure the more important complement components, i.e. C3 and C4. For this methods code 4182 (quantitative protein estimation: nephelometer or turbidometric method) should be used.

For the rare or esoteric C5 and C6 measurements, these may currently only be measured by the radial immunodiffusion method and here we recommend that code 3963 be used.

9 **Drug of abuse screening:**

(4370) Drug level in biological fluid: Monoclonal immunological
(4287) Identification of drug: Qualitative

Laboratories that are using automated analysers that produce quantitative drug results (4370); if so, the quantitative code should be used.

10 **Micro-albumin (4261) and Creatinine (4221):**

Laboratories measure both the micro-albumin and the creatinine level and report the ratio. Therefore both codes may be used.

11 Free testosterone:

Free testosterone is used to assess testosterone bio-activity status in both males and females. There are two ways of measuring free testosterone. There is a direct assay and there is a mathematical derivation from the total testosterone and SHBG levels. There are major deficiencies with the direct free testosterone assay. The derivation of the free testosterone from the total testosterone and SHBG levels is considered good practice and is far superior for this purpose as the derivation provides a far more accurate index of testosterone bio-activity.

Free testosterone testing attracts the code (4501) and sex hormone binding globulin attracts the code (4526).

BLOOD GASES:

- 1 pH, pCo₂, Std.HCO₃, BE, pO₂: (4076) maximum six per patient per 24 hours.
- 2 The following ancillary tests are included as part of the (4076) code if performed on a bloodgas analyser: Na, K Hb, Ionized Calcium, magnesium, glucose, bilirubin, urea, lactate and oximetry parameters.
- 3 Tests falling within the "ancillary test" group, which are performed on a discrete analyser (not a bloodgas analyser) located in a laboratory premises or at a point of care site and be described separately under a different requisition number for blood gases tested on the same date of service. However, this should usually only happen when the bloodgas analyser at the hospital in question is of the simple type that does not perform ancillary tests. It is, however, recognised that healthcare providers will occasionally request that such ancillary tests be performed separately in the laboratory, even when the resident bloodgas analyser is capable of performing such tests at the hospital or clinical setting.

No additional charge is applicable for saturation.

APPROPRIATE SAMA TARIFF CODING FOR VITAMIN D TESTING:

The SAMA doctors billing manual lists two possible codes for vitamin D testing. These are:

- 4492: Vitamin D3: Calcitriol (RIA)
- 4156: Vitamin D3

Radio immuno assay (RIA) is a competitive binding assay using an antibody labelled with a radiolabelled isotope as the tracer. Due to the difficulties of managing radioisotopes, assay manufacturers have moved from these to non-isotopic tracers over the years. Chemiluminescent labels are one of the alternatives tracers.

Code (4492), because it applies to a competitive binding assay for vitamin D measurement, is the appropriate code to use for competitive binding assays using tracers of any type, including isotopic and non-isotopic ones

Code (4156) is applicable to the old ELISA and other historical methods for vitamin D measurement.

CHEMISTRY GROUP TESTS/PROFILES:

CHEST PAIN PROFILE:

- | | | |
|---|---------------------|----------------|
| 1 | CK | (4132) |
| 2 | CK-MB Mass | (4152 or 4153) |
| 3 | Troponin "I" or "T" | (4161) |

HIRSUTISM:

- | | | |
|---|--|---------------------|
| 1 | Free Testosterone or Total Testosterone / SHBG | (4502 OR 4526/4501) |
| 2 | DHEA | (4500) |
| 3 | 17-OH progesterone | (4520) |

A 24 hour urine free cortisol can be added to screen for Cushing's syndrome (4499)

IMMUNOGLOBULINS:

- | | | |
|---|--------|--------|
| 1 | 1. IgA | (4182) |
| 2 | IgM | (4182) |
| 3 | IgG | (4182) |
- IgE should be separate

INFERTILITY – FEMALE:

- | | | |
|---|---------------------------------------|-----------------------|
| 1 | FSH | (4516) |
| 2 | LH | (4517) |
| 3 | Prolactin | (4537) |
| 4 | Oestradiol | (4503) |
| 5 | Progesterone (Day 21) | (4521) |
| 6 | Free Testosterone or Total testo/SHBG | (4502 OR 4526 / 4501) |
| 7 | Free T4 | (4452) |
| 8 | TSH | (4507) |
| 9 | DHEA | (4500) |

INFERTILITY – MALE:

Hormonal Infertility Male: (Profile 1)

- | | | |
|---|---------------------------------------|------------------|
| 1 | FSH | (4516) |
| 2 | LH | (4517) |
| 3 | Prolactin | (4537) |
| 4 | Free testosterone or total testo/SHBG | (4502/4526/4501) |

IRON STUDIES:

- | | | |
|---|--------------------------------|--------|
| 1 | Serum Iron | (4071) |
| 2 | Ferritin | (4528) |
| 3 | Transferrin or TIBC (not both) | (4144) |

LIPOGRAM:

(4025)

- 1 Total Cholesterol
- 2 HDL-Cholesterol
- 3 LDL-Cholesterol
- 4 Triglycerides

LIVER FUNCTION TESTS

- | | | |
|---|-------------------------------|---------------|
| 1 | 1. Total/conjugated bilirubin | (4009 / 4010) |
| 2 | Alk. Phos. | (4001) |
| 3 | Gamma GT | (4143) |
| 4 | Total protein | (4117) |
| 5 | Albumin | (3999) |
| 6 | AST | (4130) |
| 7 | ALT | (4131) |

THYROID PROFILE

- | | | |
|---|-------------|--------|
| 1 | FTB4B & TSH | (4484) |
|---|-------------|--------|

FTB3B and thyroid antibodies may be added as well, if requested, separately.

- FTB3B and thyroid antibodies may be requested by the healthcare provider on the request form or added by the pathologist in consultation with the healthcare provider. The request should be recorded by the pathologist and should include the reason/s for the request and the person who made the request.

HAEMATOLOGY

General Rules

Pathologists should define the parameters for performing reticulocyte counts in their own environment.

COAGULATION PROFILES:

Limited Screen for Bleeding Disorder

1	FBC and platelets	(3755 and 3797)
2	INR	(3805)
3	PTT	(3837)
4	Bleeding time or PFA 100	(3713 / 0201/NAPPI)
5	Fibrinogen	(3825)

Extended Bleeding Disorder Profile:

(May include the following tests amongst others)

1	FBC and Platelets	(3755 and 3797)
2	INR	(3805)
3	PTT	(3837)
4	Bleeding time or PFA 100	(3713 + 0201)
5	Fibrinogen	(3825)
6	Thrombin Time	(3841)
7	Factor VIII	(3757)
8	Von Willebrand Factor	(3758)
9	Ristocetin Co-factor	(3857)
10	Factor XIII (quantitative) or Factor XIII (qualitative)	(3757) (3744)
11	Platelet Function studies	(3795 x 6)

Additional specialized factor or other assays should preferably be performed after consultation with a laboratory haematologist. The request should be recorded by the pathologist.

DIC Screen:

1	FBC	(3755)
2	PLTS	(3797)
3	INR	(3805)
4	PTT	(3837)
5	D-Dimer (qualitative) Or D-Dimer (quantitative) And/or FDP	(3854) (3856) (3853)
6	Fibrinogen	(3825)

INHERITED THROMBOTIC SCREEN:

1	Activated Protein C Resistance	(3726)
2	Factor V Leiden (PCR)	(3974)

3	Prothrombin 20210A	(3974)
4	Protein C	(3734)
5	Protein S	(3730)
6	Antithrombin	(3735)
7	Homocysteine	(4040)

Additional specialized factor or other assays should preferably be performed after consultation with a laboratory haematologist. The request should be recorded by the pathologist.

EXTENDED THROMBOTIC SCREEN

1	Activated Protein C Resistance	(3726)
2	Factor V Leiden (PCR)	(3974)
3	Prothrombin 20210A	(3974)
4	Protein C	(3734)
5	Protein S	(3730)
6	Antithrombin	(3735)
7	Homocysteine	(4040)
8	Lupus Anticoagulant / Antiphospholipid antibody screen (as per profile below)	
9	Pre / post-stress Euglobulin Lysis time or Tissue plasminogen activator release	(3767 x 2) (3750 x 2)
10	Plasminogen	(3736)
11	Fibrinogen	(3825)
12	Thrombin time	

Additional specialized factor or other assays should preferably be performed after consultation with a laboratory haematologist. The request should be recorded by the pathologist.

LUPUS ANTI-COAGULANT / ANTIPHOSPHOLIPID ANTIBODY SCREEN:

(As a matter of good practice at least 2 tests using different assay principles should be used)

1	dRVVT (dilute Russell viper venom time)	(3737)
2	KCT (kaolin clotting time) or SCT (silica clotting time)	(3738)
3	APTT using a sensitive reagent (PTT-LA)	(3837)

If any test above is abnormal, 4 and/or 5 below are required:

4	Confirmation assay ("platelet neutralisation") of dRVVT or KCT or SCT or PTT-LA	(3737 or 3738 or 3837)
5	Mixing study of dRVVT or KCT or SCT or PTT-LA	(3737 or 3738 or 3837)
6	Anticardiolipin IgG and IgM	(3948 & 3946)
7	Anti-B2GP1 IgG and IgM	(3948 & 3946)

If indicated by results or clinical profile:

8 Antiprothrombin IgG and IgM (3948 + 3946)

HAEMOLYTIC PROFILE:

1	FBC/platelets	(3755 / 3797)
2	Reticulocytes	(3809)
3	Bilirubin total	(4009)
4	Bilirubin conjugated	(4010)
5	Haptoglobin serum	(3772)
6	LDH, serum	(4133)
7	Direct Coombs Test	(3709)
8	Indirect Coombs Test (If indicated)	(3709)

ABNORMAL HAEMOGLOBIN SCREEN:

1	Haemoglobin electrophoresis (both acid and alkaline may be done if required)	(3769)
2	HPLC may also be done in addition or as alternative to the above if indicated	(3998)
3	Column chromatography for HbA2	(3768)
4	Reticulocytes	(3809)
5	Alkali resistant haemoglobin	(3705)

It is likely that only the following will be used on the laboratory request form as profiles. This does not preclude laboratories from including additional profiles based on the principles above in their respective request forms.

- LIMITED SCREEN FOR BLEEDING DISORDER
- DIC SCREEN
- INHERITED THROMBOTIC SCREEN
- LUPUS ANTI-COAGULANT / ANTIPHOSPHOLIPID ANTIBODY SCREEN
- HAEMOLYTIC PROFILE
- ABNORMAL HAEMOGLOBIN SCREEN

BONE MARROW:

Description	Code	(A) Bone marrow obtained in the laboratory	(B) Bone marrow obtained outside of the laboratory in own rooms	(C) Bone marrow obtained outside of the laboratory and in hospital	(D) Bone marrow obtained outside of the laboratory but in theatre
Aspiration only					
Setting of sterile tray	(0202)	Y	Y	Y	Y
Aspiration needle (disposable)	(0201+nappi)	Y	Y	Y	Y
Bone marrow aspiration	(3719)	Y	Y	Y	Y

Description	Code	(A) Bone marrow obtained in the laboratory	(B) Bone marrow obtained outside of the laboratory in own rooms	(C) Bone marrow obtained outside of the laboratory and in hospital	(D) Bone marrow obtained outside of the laboratory but in theatre
Bone marrow cytology	(3717)	Y	Y	Y	Y
Consultation	(0190)	Y	Y	Y	Y
Visit hospital	(0173)	N	N	Y	N
Iron stain	(3885)	Y	Y	Y	Y
Attendance in theatre	(4544)	N	N	N	Y
Using own rooms	(0004)	Y	Y	N	N
Gloves	(02010)	Y	Y	Y	Y
Aspiration and biopsy (UNILATERAL)					
Setting of sterile tray	(0202)	Y	Y	Y	Y
Aspiration needle (disposable)	(0201+nappi)	Y	Y	Y	Y
Biopsy needle (disposable)	(0201+nappi)	Y	Y	Y	Y
Bone marrow aspiration & Biopsy	(3721)	Y	Y	Y	Y
Bone marrow cytology	(3717)	Y	Y	Y	Y
Consultation	(0190)	Y	Y	Y	Y
Visit hospital	(0173)	N	N	Y	N
Iron stain	(4589)	Y	Y	Y	Y
Attendance in theatre	(4544)	N	N	N	Y
Using own rooms	(0004)	Y	Y	N	N
Gloves	(0201)	Y	Y	Y	Y
Histology sections	As necessary: depending on what is done and how many sections are made. If done: serial step sections.				
Aspiration and biopsy (BILATERAL)					
Setting of sterile tray	(0202)	Y	Y	Y	Y
Aspiration needle (disposable)	(0201+nappi)	Y	Y	Y	Y
Biopsy needle (disposable)	(0201+nappi)	Y	Y	Y	Y
Bone marrow aspiration & Biopsy	(3721+3720)	Y	Y	Y	Y
Bone marrow cytology	(3717)	Y	Y	Y	Y
Consultation	(0190)	Y	Y	Y	N
Visit hospital	(0173)	N	N	Y	Y
Iron stain	(4589)	Y	Y	Y	N
Attendance in theatre	(4544)	N	N	N	N
Using own rooms	(0004)	Y	Y	N	
Gloves	(0201)	Y	Y	Y	Y
Histology sections	As necessary: depending on what is done and how many sections are made. If done: serial step sections.				

Pathologists may charge a consultation fee to consult with the patient in order to advise on the procedure and then charge a procedure fee when performing a bone marrow biopsy. The exceptions are:

- 1 when a pathologist has a consultation with a patient and it is decided at this consultation that the procedure will be performed at a later stage, then no consultation fee may be charged again on the day of the procedure;
- 2 when an elective biopsy is performed in the theatre and the pathologist has not consulted with the patient, then only the procedure fee may be charged.

Pathologists are allowed to charge for consultations with patients when they personally consult with the patient. The consultation must be coded as follows:

- 1 First visit in hospital: Code (0173 + 0145 + 3721)
- 2 Emergency - first hospital visit: Code (0173 + 0147 + 3721)
- 3 Patient seen at the laboratory or the pathologist's own rooms: Code (0190) / (0192) (as appropriate) + Code (3721)

If the pathologist was called out to do an emergency biopsy, modifier 0011 may be added to the procedure fee.¹

Refer to Rule L² for procedures performed at the time of a consultation: if a procedure is performed at the time of a consultation, then the fee for the consultation PLUS the fee for the procedure may be charged.

¹ The reference to modifier 0011 is a reference to this modifier as it appears in the Doctor's Billing Manual published by the South African Medical Association.

² The reference to Rule L is a reference to this rule as it appears in the doctor's billing manual published by the South African Medical Association.

SEROLOGY

GENERAL RULES

Charging of code (4451) (Quantitative HCG) when a qualitative HCG has been performed is unacceptable. Code (4450) should be used. Codes (4450) and (4451) should not, **unless specifically requested** by a healthcare provider, be billed in combination.

S- PREGNANCY TESTS:

S-HCG Qualitative 4450
S-HCG Quantitative 4451



These two tests should not be billed together. Some practices only perform the Quantitative HCG 4451 and report is as such.

RUBELLA IGM:

Affinity test or second Elisa test for confirmation of positive Rubella IgM: this should only be performed in pregnant woman.

GROUP TESTS:

RPR: Laboratories may use code (3951) (RPR Quantitative) if they perform titration on all specimens to avoid false negative results.

AUTO-IMMUNE PROFILE:

1	ANF	(3934)
2	ENA Screen	(3948 x 1)
3	Rheumatoid factor X 1 as screening test	(4182)
4	CRP	(3947)
5	FBC, platelets / ESR	(3755 / 3797 / 3743)

If the ANF is positive, up to 5 dilutions of ANF may be performed.

6 x ENA markers may be described using under the IgG ELISA code (3948) (i.e. 6 x 3948) or Western blot code (3969 x1), if the ENA screen is positive. The code used will depend on the method used by the laboratory.

HIV-MONITORING: (Adult)

1	HIV PCR (Quantitative)	(4429)
2	CD4	(3816)

VIRAL HEPATITIS:

Hepatitis B status (acute):

- | | | |
|---|-----------------------------------|------------|
| 1 | Hep. B S Ag | (4531) |
| | If positive add Hep B e Ag and Ab | (4531 X 2) |
| 2 | Hep. B S Ab | (4531) |
| 3 | Hep. B Core Ab (total) | (4531) |
| | If positive Reflex Hep B core IgM | (4531) |

Hepatitis A and B Status (acute):

- | | | |
|---|-----------------------------------|------------|
| 1 | Hep. B S Ag | (4531) |
| | If positive add Hep B e Ag and Ab | (4531 X 2) |
| 2 | Hep. B S Ab | (4531) |
| 3 | Hep. B Core Ab (Total) | (4531) |
| | If positive add Hep B core IgM | (4531) |
| 4 | Hep. A Ab (IgM) | (4531) |

Hepatitis A, B and C Status (prior exposure):

- | | | |
|---|---------------------------------------|------------|
| 1 | Hep. B S Ag | (4531) |
| | If positive add Hep B e Ag and Ab | (4531 X 2) |
| 2 | Hep. B S Ab | (4531) |
| 3 | Hep. B Core Ab (Total) | (4531) |
| | If positive add Hep B core IgM | (4531) |
| 4 | Hep. A Ab (IgM) | (4531) |
| 5 | Hep. C Ab (IgG) | (4531) |
| | If positive add qualitative Hep C PCR | (3974) |

Hepatitis A, and B Immunity Profile:

- | | | |
|---|-------------|--------|
| 1 | Hep. A IgG | (4531) |
| 2 | Hep. B S Ab | (4531) |

EBV SEROLOGY

- | | |
|-------------------|--------|
| EBV early antigen | (3948) |
| EBV VCA IgG | (3948) |
| EBV nuclear IgG | (3948) |
| EBV VCA IgM | (3946) |

Interpretive note: The titration of EBV early antigen was used by many clinicians in the mid 1980's through to 1990's as an aid in the diagnosis of chronic fatigue syndrome. There are very few clinicians who still request EBV early antigen titrations. Code 3970 has thus been deleted from SAMA billing guidelines and is no longer in use. It must be deleted from all billing guidelines.

If infectious mononucleosis (Glandular fever) is suspected, only an EBV VCA IgM (code 3946) and should be requested by the referring healthcare provider. The full EBV profile may be requested by the referring healthcare provider for other EBV-related conditions.

HIV Testing and Confirmatory Tests

- 1 Serological screening for HIV may be performed with a 4th generation HIV ELISA (combined antibody and p24 antigen ELISA).
- 2 It is each laboratory's prerogative to confirm or not confirm reactive HIV ELISA results according to whatever the Guidelines it is using or what has been requested by the referring healthcare provider. This decision must be evidence based. The use of western blot testing and 3rd generation ELISA (antibody only ELISA) are both currently deemed to be scientifically sound as confirmatory tests for HIV and are supported by international HIV testing protocols. Laboratories may also offer healthcare providers the option of HIV ELISA testing with or without confirmation on request forms.
- 3 In certain cases where the results are not clear following an appropriate screening and confirmatory test, additional tests may be required such as HIV p2 antigen ELISAs, HIV-1 and HIV-2 western blots and HIV molecular tests.
- 4 Confirmation of reactive screening HIV ELISAs by means of HIV viral load testing is an appropriate method of confirmation.

MICROBIOLOGY

General Rules

- 1 Unbundling is not permitted.
- 2 Charging for more than two sensitivities on microbiology specimens: this is allowed when clinically appropriate. A third sensitivity charge should appear in < 1% of microbiology where a third pathogen of note is isolated.
- 3 Mantoux tests are described using codes (0221 + 0201)/NAPPI code 8729308026. Mantoux reagent is supplied in multi-dose vials that expire 8 hours after opening (Manufacturers recommendations). In most cases it will therefore be necessary to charge an individual patient the full cost of the multi-dose vial.
- 4 Malaria antigen strip: code (3792) must be used.
- 5 CSF: the full CSF examination (cell count, protein, glucose, chloride) must be described using codes (4407) and (3783) as one may not unbundle the codes.

BILLING OF MICROBIOLOGY SAMPLES:

EAR SWABS:

Add fungal culture to the procedure, if sample not middle ear specimen (3901)

SWAB/ASPIRATES FROM EARS OR SINUSES

SWABS FROM EXTERNAL EAR CANAL OR SINUS

Microscopy	(3867)
Culture	(3895)
Anaerobic culture	(3909)
Fungal culture	(3901)

ASPIRATES

Microscopy	(3867)
Culture	(3895)
Anaerobic culture	(3909)

Should organisms be identified and sensitivity tests are performed, then the following charges may be used:

Identification as per organism/type	(3924/3923/3927/4652) See identification of micro organism
Sensitivity per organism	(3887/4652)

Special notes (additional charges):

Describe identification and sensitivity testing of micro-organisms as per ID and sensitivity billing as set out in the Guideline on the invoice.

- Enterobacteriaceae should be tested for ESBL production (3887)
- Beta-lactamase for Haemophilus/Moraxella (3911)
- Streptococcus pneumoniae penicillin MIC (4650)
AND cefotaxime MIC (4650) or ceftriaxone MIC if the strain screens resistant on oxacillin disc testing
- Eosinophil count (3885) on sinus aspirates

EYES SWABS OR ASPIRATES

If no history is given, set up the following procedures:

- Microscopy (3867)
- Culture (3895)

If the history indicates keratitis or endophthalmitis, fungal culture may be added. (3901)

If the history suggests keratitis, culture for acanthamoeba should be added (3879)

Special notes (additional charges):

Describe identification and sensitivity testing of micro-organisms as per ID and sensitivity billing as set out in the Guideline.

- Enterobacteriaceae should be tested for ESBL production (3887)
- Beta-lactamase for Haemophilus/Moraxella and penicillin-sensitive Staphylococcus aureus (3911)
- Viral, fungal, acanthamoeba, and chlamydia investigations need to be separately requested by the referring healthcare provider.
- Mycobacterial studies need to be separately requested by the referring healthcare provider.

SPUTUM EXAMINATION:

The following procedures are followed, with reference to best pathology practice, when sputum is sent in for microscopy, culture and sensitivity testing:

- Microscopy (3867)
- TB microscopy (Zn) (3881 ZN) or (3885) Fluorescent Stain
- Culture (3895)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type	(3924/ 3923/ 3927/4652) See identification of micro- organisms
Sensitivity per organism	(3887/4653)

Special notes:

- Eosinophil stain should be separately requested by the referring healthcare provider (3885)
- Enterobacteriaceae should be tested for ESBL production (3887)
- Beta-lactamase for Haemophilus/Moraxella (3911)
- Streptococcus pneumoniae penicillin MIC and cefotaxime MIC (4650) or ceftriaxone MIC, if strain is resistant to oxacillin on disc testing (4650)
- TB culture to be performed on one of the samples if multiple samples are submitted e.g. bronchial washings, bronchoalveolar lavage etc.
- Pneumocystis carinii detection, Legionella studies should be separately requested by the referring healthcare provider
- Viral studies (e.g. direct fluorescence) need to be separately Requested by the referring healthcare provider.

NOSE EXAMINATION:

The following procedures are followed ,with reference to best pathology practice, when nose swabs are sent in for microscopy, culture and sensitivity testing:

Microscopy	(3867)
Culture	(3895)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type	(3924/3923 /3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

Special notes:

- Enterobacteriaceae should be tested for ESBL production (3887)

- Beta-lactamase for Haemophilus/Moraxella (3911)
- Streptococcus pneumoniae penicillin MIC (4650) and cefotaxime MIC (4650) or ceftriaxone MIC if the isolates screen resistant on oxacillin disc testing
- Culture for Corynebacterium diphtheria should only be performed if separately requested by the referring healthcare provider. (3895)
- If culture for Staphylococcus aureus or MRSA is requested by the referring healthcare provider on nose swabs (this will also include swab from the groin and/or axilla), then describe using code 3893 (bacteriological culture – miscellaneous) and not under 3907, which is intended for mass screening for staphylococcal carriage in food workers.

THROAT EXAMINATION:

The following procedures are followed, with reference to best pathology practice, when throat swabs are sent in for microscopy, culture and sensitivity testing:

Microscopy (3867)
Culture (3895)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type (3924 /3923/3927/4652)
See identification of micro-organisms

Sensitivity per organism (3887/4653)

Special notes:

- Enterobacteriaceae should be tested for ESBL production (3887)
- Beta-lactamase for Haemophilus/Moraxella (3911)
- Streptococcus pneumoniae penicillin MIC (4650) and cefotaxime MIC (4650) or ceftriaxone MIC if the isolates screen resistant on oxacillin disc testing
- Culture for Corynebacterium diphtheria should only be performed if separately requested by the referring healthcare provider. (3895)

MOUTH SWABS

The following procedures are followed, with reference to best pathology practice, when mouth swabs are sent in for microscopy, culture and sensitivity testing:

Microscopy (3867)
Culture (3895)

Fungal culture (3901)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type	(3924 /3923/3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

FAECES EXAMINATION

The following procedures are followed, with reference to best pathology practice, when stools are sent in for microscopy, culture and sensitivity testing:

Microscopy	(3869)
Culture (fastidious)	(3893)
Selenite culture	(3893)
Campylobacter culture	(3879)
Cryptosporidium stain	(3885)

Notes: The Public Health Laboratory Service in the United Kingdom (“the PHLS”) also recommends culturing for campylobacter routinely and staining for Cryptosporidium routinely.

Additional charges:

- In children younger than 5 years old, and in patients older than 60 years of age, rotavirus antigen is performed (3939/3904). In patients 6 to 60 years, rotavirus should be separately requested by the referring healthcare provider in accordance with the PHLS Guidelines.
- In children younger than 5 years of age, adenovirus antigen may be performed (3939/3948). In older patients, adenovirus should be separately requested by the referring healthcare provider.
- Culture for vibrio (3895) should be separately requested by the referring healthcare provider.
- Should pathogens be cultured, they need to be identified and described accordingly.
- See section on identification for more details.

Non-lactose fermenters should be screened for non-pathogens using either urease or Singer's (code 3923).

- Should virulence genes be determined for potential EPEC strains, charge under code (4433).
- Check for ESBL producing Enterobacteriaceae then use code (3887).
Only if Disc susceptibility testing is performed
Not necessary if using Automated systems

- Sensitivity testing should be conducted on enteric bacterial pathogens, then use codes (3887/4653).
- Faecal occult blood (monoclonal: then use code (4352)) should be ordered separately by the referring healthcare practitioner.

Special notes: *Clostridium difficile* exotoxin determination is only performed on special request by healthcare provider when pseudo-membranous colitis is clinically suspected, code (3889) or (3902), depending on the method used. PCR testing (3974) is recommended since it is more accurate as it is able to detect both toxins A and B.

VAGINAL/CERVICAL AND URETHRAL SWAB EXAMINATION:

The following procedures are followed, with reference to best pathology practice, when vaginal/cervical swabs are sent in for microscopy, culture and sensitivity testing:

Microscopy	(3867)
Trichomonas	(3885)
Culture	(3895)
Yeast culture	(3901)
Mycoplasma/Ureaplasma culture	(3918 or 3917)

The PHLS Standard Operating Procedure recommends yeast culture for all vaginal, urethral and endocervical swabs.

Should organisms be identified and sensitivity tests be performed, then the following charges may be added on:

Identification as per organism/type	(3924/3923/3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

Special notes:

- Enterobacteriaceae should be tested for ESBL production on pure isolates only using code (3887)
 Only if Disc susceptibility testing is performed
 Not necessary if using Automated systems
- Beta-lactamase assay (3911) should be performed for *Neisseria gonorrhoeae* if this organism is isolated.
- Although acridine orange stain and wet preparations are less sensitive than culture, routine culture for trichomonas is not recommended.
- Anaerobic cultures should not be performed unless requested by the referring healthcare practitioner. (e.g. actinomyces in IUCDs).
- In patients with cervicitis or urethritis, a Chlamydia PCR (3974) may be performed on adequately collected samples.

URETHRAL DISCHARGE PROFILE

Urethral MCS:	as per urethral swab above
Urethral/urine Chlamydia PCR:	(3974)
Gonococcal PCR	(3974)

GENITAL ULCERATION PROFILE

HIV Elisa	(3932)
Syphilis PCR	(3974) OR
Syphilis serology	(3951+3948/3946)
Haemophilus ducreyi PCR	(3974) OR
Haemophilus ducreyi culture	(3893)
Herpes simplex virus PCR	(3974) OR
Herpes simplex virus culture	(3897/4591 x 2/3882 x 2)

CEREBROSPINAL FLUID EXAMINATIONS:

The following procedures are followed, with reference to best pathology practice, when cerebrospinal fluids are sent in for microscopy, culture and sensitivity testing:

Cell count, protein, glucose, chloride	(4407)
Microscopy (gram stain)	(3867)
Culture	(3895)
Cell count differential (stained method) (only if cells present)	(3783)
Should organisms be identified and sensitivity tests are performed, then the following charges may be used:	
Identification as per organism/type	(3924/3923/3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

Special notes:

- Capsular antigen detection use code (3939). Five capsular antigens may be determined if specially requested by the healthcare provider or if the CSF white cell count is elevated.
- Cryptococcus antigen titres are done if specially requested or if yeast cells are observed, use code (3939 x 5) for dilution titre
- Enterobacteriaceae should be tested for ESBL production – 3887
Only if Disc susceptibility testing is performed
Not necessary if using Automated systems
- Viral culture and PCR assays for herpes simplex, enteroviruses etc should be separately requested by the healthcare provider.

Should herpes simplex virus serology be ordered by the healthcare provider on CSF, then perform HSV PCR, which is the most effective test available for diagnosis.

Should Coxsackie serology be ordered by the healthcare provider on CSF, then perform enterovirus PCR.

- TB culture or TB-PCR should be separately requested by the healthcare provider.
- Syphilis serology (VDRL or syphilis IgG) needs to be separately requested by the referring healthcare provider. If automated haematology analysers, e.g. Advia, are used to screen and perform cell counts on CSF, then use the following codes:

Cell count	(3783)
CSF protein	(4419)
CSF Glucose	(4421)
CSF chloride (if performed)	(4409)

EXAMINATION OF SWABS OR ASPIRATES FROM SKIN/SUBCUTANEOUS TISSUES, WOUNDS, BURN WOUNDS AND, TISSUES:

The following procedures are followed, with reference to best pathology practice, when pus swabs from skin or subcutaneous tissues, wounds (including burn wounds), and tissues are sent in for microscopy, culture and sensitivity testing:

Microscopy	(3867)
Culture	(3895)
Anaerobic culture	(3909)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type	(3924/ 3923 /3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

Special notes:

- Enterobacteriaceae should be tested for ESBL production – 3887
- Virus culture needs to be separately requested by the healthcare provider.
- Culture for fungi (3901) if the sample is from a burn wound or from a paronychia.
- Perform a wet preparation microscopic examination (3867) on samples from liver abscess.
- AFB and mycobacteria culture must be ordered separately by the healthcare provider or after consultation with the healthcare provider e.g. sterile abscesses.

PLEURAL /PERITONEAL FLUID EXAMINATION:

The following procedures are followed, with reference to best pathology practice, when pleural or peritoneal fluid is sent in for microscopy, culture and sensitivity testing:

Microscopy (gram stain)	(3867)
Cell count	(4401)
Culture	(3895)
Anaerobic culture	(3909)
TB microscopy (Zn)	(3881)
Mycobacterium culture on one of the samples	
radiometric	(3916) OR
non-radiometric automated	(4651) OR
LJ slope	(3915) OR
TB culture bottle	0201 / NAPPI (for radiometric and non-radiometric bottles)

Should organisms be identified and sensitivity tests are performed, then the following charges may be added on:

Identification as per organism/type	(3924 /3923 /3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

- ADA should be separately requested by the healthcare provider.
- Mycobacterium PCR should be separately requested by the healthcare provider.

SYNOVIAL FLUID EXAMINATION:

The following procedures are followed, with reference to best pathology practice, when synovial fluid is sent in for microscopy, culture and sensitivity testing:

Microscopy (gram stain)	(3867)
Cell count	(4401)
Culture	(3895)
Anaerobic culture	(3909)
Crystal examination	(3878)

Should organisms be identified and sensitivity tests are performed, then the following charges may be used:

Identification as per organism/type	(3924/ 3923/ 3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

- TB cultures (and microscopy) should be separately requested by the healthcare provider.

URINE EXAMINATION:

A basic urine microscopy, culture and sensitivity consist of the following:

Chemistry	(4188)
Microscopy	(3867)
Culture	(3893)
Total viable count	(3922)

Antimicrobial substances (3928)

Should organisms be identified and sensitivity tests are performed, then the following charges may be used:

Identification as per organism/type (3924 /3923 /3927/4652)
See identification of
micro-organisms
Sensitivities (3887/4653)

Special notes:

- Direct sensitivity for urines containing significant pyuria: use code (3887).
- No identification or sensitivity testing should be undertaken if more than 2 organisms are isolated as this indicates contamination.
- In catheter or suprapubic specimens all isolates should be identified and have appropriate sensitivity testing done.
- Enterobacteriaceae should be screened for ESBL production: (3887)
 Only if Disc susceptibility testing is performed
 Not necessary if using automated systems
- Only perform bilharzia testing in patients with haematuria in local areas where bilharzia is endemic or there is travel history to an endemic area.
- Dark field microscopy should not be done unless requested by the healthcare provider.
- Bile pigments (4211) should be requested separately by the healthcare provider.
- Screening for Salmonellae (requiring selective enrichment media) should only be performed if separately requested by the healthcare provider.
- Screening for Chlamydia trachomatis via PCR should only be performed if specifically requested by the healthcare provider.
- AFB and Mycobacterium culture should be separately requested by the healthcare provider.
- If urine sample shows sterile pyuria (pus cells more than 10 cells/HPF without bacterial growth) then the following investigations should also be considered:

 AFB + TB culture,
 PCR's to exclude Chlamydia trachomatis and Neisseria gonorrhoeae, or
 Culture for Mycoplasma hominis and Ureplasma urealyticum.

BLOOD CULTURES

It is recommended that two blood culture sets should be collected instead of multiple (up to 6 sets per day) collections per day. There may, however, be rare requests by the referring

healthcare provider for multiple blood culture sets per day especially from cardiologists suspecting endocarditis.

A blood culture bottle may be described as follows:

Radiometric blood culture bottle or	(3894)
Non-radiometric blood culture or	(4651)
Standard blood culture bottle	(3891) or (3892)

PLUS:

For radiometric or non-radiometric blood culture bottles use code (0201) / NAPPI code per bottle submitted. Should organisms be identified and sensitivity tests are performed, then the following charges may be used:

On bottles with a positive signal, perform gram stain (3867) prior to setting up unnecessary identifications and sensitivity tests

Identification as per organism/type	(3924/3923/3927/4652) See identification of micro-organisms
Sensitivity per organism	(3887/4653)

MYCOBACTERIAL CULTURES:

Mycobacterial examinations may be submitted from ANY source should the healthcare provider suspect Mycobacterium involvement.

The following procedures are followed, with reference to best pathology practice, when a sample is submitted for Mycobacterial examination:

TB microscopy	(3881) (ZN) or (3885) (fluorescence auramine)
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Mycobacterium culture:	
radiometric	(3916)
non-radiometric automated	(4651)
LJ slope	(3915) PLUS
TB culture bottle	radiometric and non-radiometric 0201 / NAPPI

If an acid fast bacilli is requested by the referring healthcare provider and an auramine stain is performed on a concentrated sample, then one may use code (4657).

Identification of Mycobacterium is performed using any one of the following methods:

DNA probes (e.g. Accuprobe)	(4431) or
Chemical methods (NAP)	(3929) or
Polymerase chain reaction	(4434) or
HPLC	(4656)

Direct molecular assay to detect mycobacteria (4434) in clinical samples.
It is strongly suggested TB culture be performed when molecular tests to detect Mycobacteria if patient samples are negative.

NOTES:

PCR assay to detect resistance genes to INH and rifampicin:

A rapid PCR may be performed on cultured isolates or on clinical samples which are AFB positive to detect INH- and/or rifampicin resistance, use code (3974 x 1).

Second line molecular testing may be performed (second (3974)) if the organism is either rifampicin and/or INH- and/or rifampicin resistance then use code (3974 x 1).

Phenotypic (conventional) antituberculous susceptibility testing may be performed according to the laboratory's own algorithms.

TB-spot / Quantiferon assays:

The indirect assays to detect latent tuberculosis (TB-spot tests or the Quantiferon assay) are performed on request by the referring healthcare provider on blood samples using code (3978 x 1).

FUNGAL CULTURES:

Fungal cultures may be submitted from ANY source if the healthcare provider requests or suspects a fungal aetiology e.g. hair, nail, skin, pus, sputum, CSF, vaginal source.

The following procedures are followed, with reference to best pathology practice, should a sample be submitted for fungal examination:

Microscopy	(3867)
Fungal culture	(3901)

Should organisms be identified and sensitivity tests are done, the following charges should be used:

Mould/yeast identification	(3868)
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Special notes:

MIC sensitivity testing using RPMI media may be described using code (4650) per antifungal agent for deep-seated infection or on the request of the healthcare provider.

IDENTIFICATION CHARGES:

Staphylococcus aureus	(3923)
Streptococcus: beta-haemolytic	(3923 + 3927)
Streptococcus: non-haemolytic	(3923)
Streptococcus: alpha-haemolytic	(3923)
Haemophilus	(3923)
Haemophilus influenzae serotyping b	(3925)
Neisseria	(3924)
Enterobacteriaceae - short	(3923)
Enterobacteriaceae - extended	(3924)
Yeasts and moulds	(3868)
Mycobacterium (DNA-probe)	(4431)
Mycobacterium (NAP)	(3929)
Microscan Rapid Panels	(4652)

Notes:

- Limit identification to 2 organisms for midstream urine- and sputum samples.
- For suprapubic and catheter urine samples, all isolates need be identified.
- In pus swabs (non-genital) and normally sterile fluids, all pathogens need to be identified.
- Automated identification systems, are superior to conventional or routine identification and susceptibility systems as they are quicker and more likely to detect resistance. They are recommended for testing on all samples including urine when a full identification and susceptibility is required. As multi-drug resistant organisms are also communicable, this technology is appropriate for all specimen sources and is not restricted to hospital acquired infections only.

SENSITIVITY CHARGES:

- 1 Use code (3887) per organism isolated.
- 2 Extended spectrum beta-lactamase screening (3887) should be looked for in all Enterobacteriaceae (not pseudomonas and non-fermenters). Only if Disc susceptibility testing is performed. Not necessary if using automated systems.
- 3 Assess for vancomycin resistant enterococci on Enterococcus species using a vancomycin breakpoint screen (code 3887).
- 4 If additional antibiotics, which are not routinely used in the antibiogram, are tested because of multi-drug resistance, then a once-off additional charge using code (3887) may be used for these additional antibiotic(s).
- 5 Assessment of teicoplanin resistance routinely using breakpoint methodology (3887) for coagulase negative Staphylococcus if the laboratory is using disc-screening methods.
- 6 Assessment of methicillin resistance routinely using a chromogenic agar plate with cefotoxin methodology (3887) for Staphylococci.

7 MICs (4650) for:

- a) Streptococcus pneumoniae strains that are resistant to oxacillin on disc screening -MIC for penicillin (4650) and cefotaxime (4650) or ceftriaxone (4650);
- b) Vancomycin resistant enterococci - MIC for vancomycin (4650) if resistant on breakpoint screening;
- c) Fungi - isolates from deep seated (normally sterile sites) or on request: 4650 per antifungal tested;
- d) Anaerobes - isolates from deep seated (normally sterile sites) or on request: 4650 per antibiotic tested;
- e) If the breakpoint screening methods with vancomycin and/or telcoplanin show a resistant Staphylococcus, this needs to be confirmed using MIC and are described under code 4590 as MIC for vancomycin, and under code 4590 as MIC for telcoplanin;
- f) beta-lactamase of all penicillin sensitive staphylococci;
- g) Penicillin E-test on viridians Streptococci from sterile sites;
- h) Vancomycin and teicoplanin e-test on all methicillin resistance S aureus strains from sterile sites; and
- i) Ceftazidime and ciprofoxacin e-test on all Stenotrophomonas strains.

Miscellaneous cost saving measures:

Instead of performing extensive identification on all microorganisms cultured, certain quick tests may be performed to differentiate significant pathogens from normal flora. Examples include:

- 1 suspicious organism resembling Neisseria from genital tract samples - perform oxidase (3923) if negative. If positive, extended identification is required (3924);
- 2 Gram-stain (3867) on blood cultures showing a positive signal. This will assist in setting up the correct identifications and sensitivities; and
- 3 Faeces: Non-lactose fermenters should be screened for non-pathogens using either urease or Singer's (code 3923) since this may save costs on expensive identifications.

PROFILES ENCOMPASSING SEVERAL DISCIPLINES OF PATHOLOGY

ARTHRITIS PROFILE:

1	ESR	(3743)
2	CRP	(3947)
3	Rheumatoid factor X 1	(4182)
4	Uric acid	(4155)

ANTENATAL PROFILE:

(Without HIV)

1	FBC +PLATELETS	(3755+3797)
2	RPR & (TPHA OR FTA OR IgG)	(3949 / 3948)
3	Blood grouping	(3764 + 3765)
4	Indirect Coombs RHA	(3709 X 2)
6	Rubella IgG/IgM	(3946 and / 3948)
7	Hep. B S Ag	(4531)

With HIV (3932)

BILLING OF TRANSPORT COSTS:

Transport costs are not included in the test price.

Transport costs may ONLY be charged if submitting samples to a third party reference laboratory, with no affiliation to the referring laboratory.

The invoice for transport costs must be available for scrutiny or preferably sent to the patient with the account.

As many medical schemes do not pay for the transport services, a cash upfront payment may be requested by the laboratory from the patient at the discretion of the laboratory at the time of collection or submission.