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| **1.** | **PURPOSE:** |
|  | 1.1 | To describe the procedure of Malaria screening |
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| **2.** | **DEFINITIONS:** |
|  | 2.1 | **MALARIAL PARASITE:** Plasmodium (having species vivax, falciparum, ovale, and malariae). |
|  | 2.2 | **THIN BLOOD SMEAR:** A smear made by a drop of blood spreaded on a glass slide by the help of another glass slide until the whole of the drop is spreaded evenly. |
|  | 2.3 | **SPREADER:** A smooth-edged disposable glass slide used to spread a drop of blood placed over another glass slide. |
|  | 2.4 | **THICK BLOOD SMEAR:** A smear made by a drop of blood spreaded on a glass slide by the help of another glass slide until the whole of the drop is spreaded evenly over an area about four times its original area. |
|  | 2.5 | **LABELLING:** It’s the process of writing down unique ID on the smear. Correct labelling of malaria blood films is important to ensure that the sample and the data correspond to the patient. The integrity of the diagnosis may be compromised by unlabeled or incorrectly labelled blood films. Labelling is important even if only one slide is to be prepared.Labelling of malaria blood films also facilitates cross-checking of quality control slides from subnational levels at the national reference laboratory. |
|  | 2.6 | **BUFFERED WATER** for malaria staining: Water having a pH of 7.2 |
|  | 2.7 | **SCANNER:** A lens of compound microscope having power of 4x used to scan the smear. |
|  | 2.8 | **LOW POWER LENS:** A lens of compound microscope having power of 10x. |
|  | 2.9 | **OIL IMMERSION LENS:** A lens of compound microscope having power of 100x. |
|  | 2.10 | **RING TROPHOZOITE:** It is the initial feeding or growing stage of Plasmodium in which it appears as a ring. |
|  | 2.11 | **AMOEBOID TROPHOZOITE:** It is the late feeding or growing stage in which the cytoplasm expands and looks like having amoeboid shape. |
|  | 2.12 | **SCHIZONT:** It is the dividing stage in which the Nucleus of the parasite divides. |
|  | 2.13 | **GAMETOCYTE:** It is the sexual, non-replicating blood-stage forms of Plasmodium spp. that are transmission agents to mosquitoes. |
|  | 2.14 | **PARASITE DENSITY:** It means number of asexual forms of Plasmodium per unit volume of blood. |
|  | 2.15 | **ASEXUAL FORMS:** It means Ring trophozoites, Amoeboid trophozoites, Immature schizonts and Mature schizonts. |
|  | 2.16 | **SEXUAL FORM:** It means gametocytes (of Plasmodium). |
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| **3.** | **POLICY:** |
|  | 3.1 | The technician/laboratorian will make a thin blood smear intended to be stained by a Romanowsky stain. |
|  | 3.2 | The technician/laboratorian will make a thick blood smear intended to be stained by a Romanowsky stain (eg Giemsa stain) for detecting presence of Plasmodia. |
|  | 3.3 | The technician/laboratorian will label Malaria blood smear. |
|  | 3.4 | The technician/laboratorian will stain a thin blood smear and a thick blood smear by Giemsa stain, a type of Romanowsky stains. |
|  | 3.5 | The technician/laboratorian will detect the presence of Plasmodium and will differentiate between its species ie vivax, falciparum, ovale, and malariae on a stained blood smear by using compound binocular light microscope.Identification of the species and stages of malarial parasites and determination of their density is crucial in clinical management of malaria patients, drug efficacy trials, malaria epidemiological surveys and control programs. Therefore, malaria diagnoses based on examination of blood films must be correct, with an accurate parasite count.Examination of blood films allows also detection of several blood pathogens, morphological diagnosis of anemia and identification of several hematological disorders, which must be reported by the microscopist. |
|  | 3.6 | The technician/laboratorian will report any other critical abnormality detected eg blasts. |
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| **4.** | **PROCEDURE:** |
|  | 4.1 | **Principle :** |
|  |  | 4.1 | Giemsa solution is composed of eosin and methylene blue (azure). The eosin component stains the parasite nucleus red, while the methylene blue component stains the cytoplasm blue. |
|  | 4.2 | **Reagent Storage And Stability:** |
|  |  | 4.2.1 | Methanol (Note: Methanol is inflammable and highly toxic if inhaled or swallowed; it can cause blindness and even death if swallowed in any quantity. Avoid contact and inhalation. When it is not in use, it should be stored in a locked cupboard, stored tightly closed at room temperature at dark place. |
|  |  | 4.2.2 | Giemsa stain should be stored tightly closed at room temperature at dark place. |
|  |  | 4.2.3 | Buffered water should be made fresh. |
|  | 4.3 | **Specimen storage:** |
|  |  | 4.3.1 | The blood should be preferably fresh before making smear. |
|  |  | 4.3.2 | If making smear is not preferred at the time of receiving blood specimens, then refrigerate blood specimens at 2 to 8 °C.*NOTE: Refer to SOP for Retention of Specimens (HBRL-HEM-SOP-019)* |
|  | 4.4 | **Requirements:** |
|  |  | 4.4.1 | **Equipments:** |
|  |  |  | 4.4.1.1 | Digital timer 60 min with alarm |
|  |  |  | 4.4.1.2 | Micropipette adjustable volume of 5 to 100 µL, with relevant tips |
|  |  |  | 4.4.1.3 | Micropipette adjustable volume of 100 to 1000 µL, with relevant tips. |
|  |  |  | 4.4.1.6 | pH meter, or Litmus paper |
|  |  |  | 4.4.1.7 | Compound Binocular Light Microscope |
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|  |  |  | 4.4.1.8 | Electronic cell counter |
|  |  | 4.4.2 | **Non-consumables:** |
|  |  |  | 4.4.2.1 | Slide box |
|  |  |  | 4.4.2.2 | Laboratory gowns |
|  |  |  | 4.4.2.3 | Tube holder/stand |
|  |  |  | 4.4.2.4 | Rack for staining slides |
|  |  |  | 4.4.2.5 | Rack for drying slides vertically |
|  |  |  | 4.4.2.6 | Staining jar with lid |
|  |  |  | 4.4.2.7 | Microscope cover |
|  |  |  | 4.4.2.8 | Safety glasses, spare for visitors |
|  |  | 4.4.3 | **Consumables:** |
|  |  |  | 4.4.3.1 | Disposable Gloves |
|  |  |  | 4.4.3.2 | Biohazard waste box |
|  |  |  | 4.4.3.3 | Sharps container |
|  |  |  | 4.4.3.4 | Lead pencil or Glass-writing Red grease-pencil or Diamond-tipped pencils |
|  |  |  | 4.4.3.5 | Glass slides measuring 75x25 mm in length and 1 mm in thickness (with frosted ends for labelling) |
|  |  |  | 4.4.3.6 | Filter paper |
|  |  |  | 4.4.3.7 | Slide label 14 mm diameter |
|  |  |  | 4.4.3.8 | Glass Coverslip, 24 x 50 mm  |
|  |  |  | 4.4.3.9 | Clean glass/plastic tubes |
|  |  | 4.4.4 | **Specimen:** |
|  |  |  | 4.4.4.1 | Capillary or EDTA-anticoagulated whole blood.*NOTE: Capillary blood is preferred over EDTA- anticoagulated whole blood as the former provides forms of Plasmodium stuck in microvasculature.* |
|  |  | 4.4.5 | **Reagents:** |
|  |  |  | 4.4.5.1 | Methanol  |
|  |  |  | 4.4.5.2 | Giemsa stain |
|  |  |  | 4.4.5.3 | Distilled water buffered to 7.2 for Malaria smears  |
|  |  |  | 4.4.5.4 | Cedar wood oil |
|  |  |  | 4.4.5.5 | Lens cleaning solution |
|  |  |  | 4.4.5.6 | Xylene |
|  | 4.5 | **Procedure:** |
|  |  | 4.5.1 | **Making Thin smear of blood:** |
|  |  |  | 4.5.1.1 | Mix the blood specimen. |
| 4.5.1.2 | Place a clean glass slide on a horizontal surface. |
| 4.5.1.3 | Take adequate volume of Capillary or EDTA-anticoagulated whole blood by micropipette. |
| 4.5.1.4 | Add on the glass slide at a place where a smear of reasonable length can be made, usually at one fourth of the length of the slide or about 1 cm from one end. |
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| 4.5.1.5 | Without delay, place the spreader in front of the drop of blood at an angle of 30 degrees to the slide. Move it to touch the drop. Allow the blood to move towards both corners of the edge of the spreader. Spread the drop firmly but gently towards the opposite end of the glass slide without any interruptions. The spreader must not be lifted off until the last trace of blood has been spread out The smear must end before approaching the edge of the glass slide, usually at three fourth of its length or 1 cm before the end of the slide. With a correctly sized drop, the smear should be about 3 cm in length. |
| 4.5.1.6 | Allow the smear to air dry. |
| 4.5.1.7 | Label the smear by writing the specimen ID on the thick part (aka head) of the smear, by using a pencil or edge of a glass slide. |
| 4.5.1.8 | Fix the smear by dipping in a jar containing a fixative (usually methanol but ethanol can be used as well) for 15 minutes. |
| 4.5.1.9 | Allow to air dry. |
| 4.5.1.10 | The ideal thickness is such that on microscopy there is some overlap of red cells throughout much of the smear's length. The leukocytes should be easily recognizable throughout most of the smear. |
|  |  | 4.5.2 | **Making Thick blood smear:** |
|  |  |  | 4.5.2.1 | Mix the specimen. |
| 4.5.2.2 | Place a clean glass slide on a horizontal surface. |
| 4.5.2.3 | Take adequate volume of Capillary or EDTA-anticoagulated whole blood by micropipette. |
| 4.5.2.4 | Place a small drop on the glass slide. If making thick and thin smear on the same slide then place on an area close to one end of the slide. |
| 4.5.2.5 | Spread it out with a disposable glass slide to cover an area about four times its original size. *NOTE: Using a glass slide has an advantage of creating scratches over the glass slide thus making it rough and more likely to hold the thick smear during washing phase.* |
| 4.5.2.6 | The correct thickness for a satisfactory smear will have been achieved if with the slide placed on a newspaper, small print is just visible. |
| 4.5.2.7 | Allow the smear to air dry for 30 minutes.*NOTE: Smears that are not completely dry may wash off in the stain.* |
| 4.5.2.8 | Label the smear by writing the specimen ID on the frosted end of the slide by using a lead pencil. A paper label should be affixed to the slide later.*NOTE: In a computerized laboratory, bar-coded specimen* *identification labels are convenient and preferable. These should have the patient's name, the date, and the laboratory number as well as the bar code.* |
| 4.5.2.9 | Fix the smear by dipping in a jar containing a fixative (usually methanol but ethanol can be used as well) for 15 minutes. Smears should never be left unfixed for more than a few hours.*NOTE: If smears are sent to the laboratory by post, it is essential that when possible they are thoroughly dried and fixed before dispatch.*  |
| 4.5.2.10 | Prevent any contact with water before fixation is complete. Allow to air dry. |
|  |  | 4.5.3 | **Labelling smear:** |
|  |  |  | 4.5.3.1 | Check the information of the patient or blood donor from the request form. |
| 4.5.3.2 | Record it accurately in the log book. |
| 4.5.3.3 | Use the lead pencil to write the following on the frosted end of the glass slide: Laboratory code, Patient identification number or code as recorded in the log-book, date of collection.Example: MP/99901/6/2022 |
| 4.5.3.4 | If slides with a frosted end are not available, details can be written on the thicker, blunt end of the thin blood smear with a lead pencil. Do not lick the end of the lead pencil during use.*NOTE: Do not use a ball point or gel pen to label the slides, as the ink will spread when the film is fixed.* |
|  |  | 4.5.4 | **Giemsa staining:** |
|  |  |  | 4.5.4.1 | The necessary material must be available before the procedure. |
| 4.5.4.2 | Take a clean glass tube. |
| 4.5.4.3 | Label it as 5% Giemsa. |
| 4.5.4.4 | Add 950 µL Buffered water (distilled water at pH 7.2) to the tube. |
| 4.5.4.5 | Place a filter paper over the tube and pour 50 µL Giemsa stain. |
| 4.5.4.6 | Place the fixed, dried & labelled blood smear slides individually on a horizontal surface for staining purpose ensuring that they are not touching each other. |
| 4.5.4.7 | By using a micropipette, take 1000 µL of 5% Giemsa stain to completely cover a thick smear & a thin smear, for 20 - 30 minutes. *NOTE: Avoid pouring the stain directly onto the smears.**NOTE: Internal quality control of the stain (as mentioned in the table at 4.5.4.14) will indicate the optimum staining time.* |
| 4.5.4.8 | Flood the slides gently with buffered water to float off the iridescent “scum” on the surface of the stain. Water buffered to 7.2 pH should be poured onto the slides from the thin smear end to avoid undue disturbance and washing-off of the thick films. Allow air dry. *NOTE: The pH of the water used for rinsing is important, as acidic water may decolorize the films. It is therefore recommended that slides be rinsed with the same buffered water that is used for staining and therefore has a pH of 7.2.* |
|  |  |  | 4.5.4.9 | Remove the slides one by one and place them, thick film downwards, in a drying rack to drain and dry, making sure that the thick film does not touch the edge of the rack. Do not blot. |
| 4.5.4.10 | A well-stained smear will be having a greyish violet colour on macroscopy (naked-eye appearance). |
| 4.5.4.11 | Ensure proper labelling of the smear. |
| 4.5.4.12 | Waste all used gloves, tips and tubes according to the relevant waste disposal policy. |
|  |  |  | 4.5.4.13 | **Use positive and negative smears as Quality Control. If unavailable, use colour of blood cells mentioned in 4.5.4.14 as Internal Quality Control.** Change timing of stain and verify pH for desired result. |
|  |  |  | 4.5.4.14 | Following are the expected staining colours: |
|  |  |  |  | **Cell Structure** | **Colour at pH 7.2** |
| **RBC** | Reddish brown |
| **Platelets** | Violet |
| **Cell nuclei** | Violet |
| **Neutrophil granules** | Light violet |
| **Eosinophil granules** | Reddish to red-brown |
| **Basophil granules** | Dark violet |
| **Lymphocytes** | Plasma blue |
| **Monocytes** | Plasma grey blue |
| **Plasmodium** | Nuclei light red; cytoplasm blue |
|  |  | 4.5.5 | **Microscopy for Malarial Parasite:** |
|  |  |  | 4.5.5.1 | Place the slide having Giemsa-stained blood smear on the stage of microscope. Position the thick smear in line with the scanner objective lens. |
| 4.5.5.2 | Switch on the microscope, and adjust the light source optimally and find the focus by looking through the ocular and the scanner followed by 10x objective. |
| 4.5.5.3 | Scan the blood smear for parasites and blood elements. Select part of the smear that is well stained and has evenly distributed white blood cells. |
| 4.5.5.4 | Place a small drop of immersion oil on the thick smear. To avoid cross-contamination, ensure that the immersion oil applicator never touches the slide. |
| 4.5.5.5 | Switch the 100x oil immersion objective over the selected portion of the thick smear. Use the fine focus adjustment to see the image clearly. Raise the mechanical stage to avoid damaging the slide. |
| 4.5.5.6 | Using the fine adjustment, focus on the cell elements, and confirm that the smear is acceptable for routine examination: 15–20 white blood cells per thick smear field will give a satisfactory film thickness. Smears with fewer white blood cells per field will require more extensive examination. |
| 4.5.5.7 | Start with the field on the top left part of the smear, and then move the slide to the right, field by field. |
| 4.5.5.8 | **Determining whether a THICK smear contains malarial parasites and identifying the species:** A minimum of 100 high-power fields must be examined before a thick smear can be declared as having “No malaria parasites seen”. If possible, the whole thick film should be scanned.*NOTE: If 5 min are spent examining a thick film, this is equivalent to about 1 h spent in traversing a thin film.* |
| 4.5.5.9 | If parasites are found, scan additional 100 fields to increase the chance of identifying mixed infections. |
| 4.5.5.10 | **Examination of the THIN blood smear to confirm species and mixed-infection:**The thin blood smear should always be examined to identify parasite species definitively. The thin smear allows visualization of parasite and red cell morphology, unlike the thick one. Perform an examination at the feathery end or edge of the thin smear. |
| 4.5.5.11 | Identify and record all species and stages observed in the malaria microscopy blood register. |
| 4.5.5.12 | To confirm the parasite species or mixed infections after examining the thick smear, examine the thin smear. |
| 4.5.5.13 | Place a drop of immersion oil on the feathered edge of the thin smear. |
| 4.5.5.14 | Move from the 10x lens to the 100x oil immersion lens. |
| 4.5.5.15 | Read the thin or feathery edge of the smear, moving from one field to the next, horizontally or vertically. |
| 4.5.5.16 | Continue examining the thin smear until the presence and species of malaria parasites have been confirmed. Identify and record all species and stages observed in the malaria microscopy blood register. |
|  |  | 4.5.6 | **Malarial parasite counting:** |
|  |  |  | 4.5.6.1 | *NOTE: Before starting counting, examine 100 fields of the thick smear to detect the presence of malaria parasites at 100x oil immersion.* |
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| 4.5.6.2 | **Performing a parasite count on a THICK film and calculating** **parasite density:** |
| 4.5.6.3 | Place the glass slide on the microscope stage. This allows a standardized approach for the start point for counting and also to record parasite locations using the marked divisions on the slide holder. |
| 4.5.6.4 | If malaria parasites are present, count asexual forms (in either single or mixed species infections) *without sexual (gametocyte) forms, which are not counted but just reported*. In mixed infections, all asexual parasites are counted together and the presence of multiple species is reported. |
| 4.5.6.5 | Starting at the top most part of the smear, look for a field with a good number of white blood cells are observed together and start counting. |
| 4.5.6.6 | Using an electronic cell counter (or a Tally counter), count parasites and white blood cells simultaneously by clicking on the assigned key as parasites or white blood cells are observed. If two tally counters are being used use one for the WBCs and the other for parasites. |
| 4.5.6.7 | After counting all the parasites and white blood cells in one field, move to the next field and repeat the same counting procedure and so on. Be careful not to overlap fields. |
| 4.5.6.8 | Depending on the number of parasites observed, stop counting after you have examined 200 or 500 white cells. • If you have counted ≥ 100 parasites in 200 white cells, stop counting, and record the results as the number of parasites per 200 white cells. • If you have counted ≤ 99 parasites in 500 white cells, stop counting, and record the results as the number of parasites per 500 white cells.  |
| 4.5.6.9 | Count all parasites and white cells in the final field. |
| 4.5.6.10 | Record the actual numbers of parasites and white cells counted. |
| 4.5.6.11 | When counting is completed, calculate the parasite density on the basis of the patient’s actual white cell count. If this is not available, use an estimated average white cell count of 8000/μL.Use the following formula for the calculation:  |
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| 4.5.6.12 | *NOTE****:*** *If ≥ 100 parasites are present in each field of a thick smear under the 100x objective, calculate the parasite count on the thin film.* |
| 4.5.6.13 | **Performing a parasite count on the THIN film and calculating parasite density:** |
| 4.5.6.14 | If infected red blood cells are present, count all parasitized red blood cells. **If sexual forms (gametocyte) are seen, do not count them, but report them**. In mixed infections, all parasitized red blood cells are counted together, and the presence of multiple parasite species is reported.  |
| 4.5.6.15 | Using a multiple type tally counter, count parasitized and other red blood cells by clicking the assigned keys for parasitized and non-parasitized red blood cells. If you have two tally counters, use one for parasitized red blood cells and the other for non-parasitized red blood cells. |
| 4.5.6.16 | After counting all the parasitized and others red cells in one field, record the result, move to the next field, and continue the same counting procedure. |
| 4.5.6.17 | After examining 20 fields of thin film, stop counting, and record all parasitized and other red cells. |
| 4.5.6.18 | When counting is completed, calculate the parasite density from the patient’s actual red cell count. If this is not available, use an estimated average red cell count of 5 000 000/ μL and the following formula. Note that the final result is rounded to the nearest whole number. |
| 4.5.6.19 | FORMULA:Number of parasites per μL blood: |
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|  | **4.6** | **Interpretation Of Results:** |
|  |  | 4.6.1 | Identify the species (according to criteria 7.5.2): |
| **Species** | **Description** |
| **P. vivax** | **Infected RBC:** being younger is larger. Schüffner dots seen.**Ring-shaped trophozoites:** Thick, 3 µm in diameter, Blue cytoplasmic ring and colourless vacuole, Usually single red chromatin seen.**Schizonts:** contain 12-24 merozoites.**Gametocytes:**  Spherical, compact, almost fills cell; single Nucleus. |
| **P. falciparum** | **Infected RBC:** has normal size. Maurer's clefts/dots seen.**Ring-shaped trophozoites:** Fine, 1.5 µm in diameter. Single or double red chromatin is seen. Accolé forms seen.**Schizonts:** contain 18-24 merozoites; rarely seen.**Gametocytes:** Banana-shaped, Diffuse chromatin, single nucleus. |
| **P. ovale** | **Infected RBC:** slightly enlarged, having oval shape, with tufted ends. Schüffner dots.**Ring-shaped trophozoites:** Thick, compact.**Schizonts:** contain 8-12 merozoites.**Gametocytes:** Oval; similar to but smaller than *P. vivax*. |
| **P. malariae** | **Infected RBC:** Normal/microcytic; stippling not usually seen.**Ring-shaped trophozoites:** Very small, compact rings; Later Trophozoite is like a band across cell, with coarse brown to black pigment; deep blue cytoplasm.**Schizonts:** contain 6-12 merozoites.**Gametocytes:** Round; similar to *P. vivax* but smaller. |
|  |  | 4.6.2 | Report as following:**1. When Plasmodium is not found:** No Malarial Parasite seen.**2. When Plasmodium is found:** Report **the** **Genus, the Species, the Stages and the Parasite density** and **follow SOP of** **Critical reporting**.(GRL-IPP-000)*(Example:**Ring trophozoites, Schizonts and Gametocytes of Plasmodium vivax seen.**Malarial Parasite density=100/µL)* |
|  |  | 4.6.3 | False Negative smears can be observed in partially-treated cases and in cases of sequestration of parasitized cells in deep vascular beds. |
|  |  | 4.6.4 | Duration of illness, level of parasitemia, and method of examination have abearing on the result. |
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|  |  | 4.6.5 | TAT for STAT test is 1 hour and for ROUTINE is 4 hours. |
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| **5.** | RESPONSIBILITY: |
|  | 5.1 | Laboratory Technician runs the controls and tests. |
|  | 5.2 | Section Supervisor performs microscopy, conducts periodic monitoring of records to determine completeness of records & compliance to the policy, and enforces corrective action as required. |
|  | 5.3 | Department Head reviews results particularly the abnormal results and ensures that all policies mentioned are enforced. |
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| **6.** | EQUIPMENT AND FORMS: |
|  | 6.1 | QC log book (LAB-HEM-017-F01) |
|  | 6.2 | Daily Giemsa staining for Malaria Worksheet (LAB-HEM-017-F02) |
|  | 6.3 | Newspaper |
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| **7.** | REFERENCE: |
|  | 7.1 | **Making Thin smear:** |
|  |  | 7.1.1 | Dacie and Lewis PRACTICAL HAEMATOLOGY, 12th Edition. page 50-51 |
|  | 7.2 | **Making Thick smear:** |
|  |  | 7.2.1 | Dacie and Lewis PRACTICAL HAEMATOLOGY, 12th Edition. page 58 |
|  | 7.3 | **Labelling smear:** |
|  |  | 7.3.1 | WHO. Basic malaria microscopy. Part I. Learner’s guide. Second edition. Geneva: 2010 |
|  | 7.4 | **Giemsa staining:** |
|  |  | 7.4.1 | Dacie and Lewis PRACTICAL HAEMATOLOGY, 12th Edition. page 59. |
| 7.4.2 | Description for Giemsa stain MS401 by Crescent Diagnostics |
| 7.4.3 | GIEMSA STAINING OF MALARIA BLOOD FILMS MALARIA MICROSCOPY STANDARD OPERATING PROCEDURE – MM-SOP-07A by WHO |
|  | 7.5 | **Microscopic detection of Malarial parasite:** |
|  |  | 7.5.1 | MALARIA MICROSCOPY STANDARD OPERATING PROCEDURE – MM-SOP-08 by WHO |
|  |  | 7.5.2 | Dacie and Lewis PRACTICAL HAEMATOLOGY, 12th Edition. page 101. |
|  | 7.6 | **Malaria parasite counting:** |
|  |  | 7.6.1 | MALARIA MICROSCOPY STANDARD OPERATING PROCEDURE – MM-SOP-09 |
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|  | **Name** | **Title** | **Signature** | **Date** |
| **Prepared by** |  | Haematologist |  |  |
| **Reviewed by** |  |  |  |  |
|  | Head of quality and Medical Director |  |  |
| **Approved by** |  | Head of quality and Medical Director |  |  |
| **Approved by** |  | Lab Director |  |  |