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Anilkumar.G, vs Priya.N,

Anilkumar.G, vs Priya.N,

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Court : Kerala

Decided On : Nov-18-2021

Judge : Honourable the Chief Justice Mr.S.Manikumar,Honourable Mr. Justice Shaji P.Chaly

Appeal No. : Con.Case(C)/672/2019

Appellant : Anilkumar.G,

Respondent : Priya.N,

Judgement :

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR & THE HONOURABLE MR. JUSTICE SHAJI P.CHALY THURSDAY, THE 18TH DAY OF NOVEMBER 2021 / 27TH KARTHIKA, 1943 WP(C) NO.19741 OF 2018 PETITIONER: ANILKUMAR.G AGED 42 YEARS, S/O. GANGADHARAN (LATE), ANACKANATTU HOUSE, MANIYARANKUDY P.O., IDUKKI - 685 602. BY ADVS. SRI.J.JULIAN XAVIER SRI.FIROZ K.ROBIN RESPONDENTS: 1 STATE OF KERALA REP.BY ITS SECRETARY, HEALTH AND FAMILY WELFARE DEPARTMENT, GOVERNMENT SECRETARIAT, THIRUVANANTHAPURAM - 695 001. 2 DISTRICT

MEDICAL OFFICER OFFICE OF THE DISTRICT MEDICAL OFFICER, IDUKKI - 685 561. 3 IDUKKI DISTRICT PANCHAYAT OFFICE OF THE IDUKKI DISTRICT PANCHAYAT, IDUKKI - 685 561, REP.BY ITS SECRETARY. 4 VAZHATHOPE GRAMA PANCHAYAT REP.BY ITS SECRETARY, VAZHATHOPE, IDUKKI DISTRICT - 685 602, REP.BY ITS SECRETARY. 5 HEALTH INSPECTOR PRIMARY HEALTH CENTRE, VAZHATHOPE, IDUKKI DISTRICT - 685 602. 6 ENVIRONMENTAL ENGINEER POLLUTION CONTROL BOARD, THODUPUZHA, IDUKKI DISTRICT - 685 602. 7 JOY SEBASTIAN PROPRIETOR, J.K. DIAGNOSTIC CENTRE, CHERUTHONI, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI DISTRICT - 685 602. 8 RAJI E.R. ITTIYEKKAL, PROPRIETOR NEW MODERN LABORATORY, CHERUTHONI, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI DISTRICT - 685 602. 9 JOSE T.J. PROPRIETOR, BHARATH DIAGNOSTIC CENTRE, CHERUTHONI, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI DISTRICT - 685 602. ADDL.R10 JABBAR A.M NEW MODERN DIAGNOSTIC CENTRE, CHERUTHONI, IDUKKI COLONY P.O., IDUKKI-685 602. ADDL.R11 ALIAMMA C.T BARATH DIAGNOSTIC LABORATORY, CHERUTHONI, IDUKKI COLONY P.O., IDUKKI-695 602.

(ADDL.R10 AND R11 ARE IMPLEADED AS PER ORDER

DATED 08/10/2018 IN IA.02/2018) BY ADVS. V.TEK CHAND, SR. GOVERNMENT PLEADER SRI.JIMMY GEORGE (THADATHIL) SRI.JOSEPH KODIANTHARA (SR.) SMT.V.GEETHA POTTI SRI.BABY MATHEW SMT.K.T.MARY SRI.UNNIKRISHNAN V.ALAPATT, SC, IDUKKI DISTRICT PANCHAYATH JOICE GEORGE THIS WRIT PETITION (CIVIL) HAVING COME UP FOR ADMISSION ON 18.11.2021 ALONG WITH WPC 5166/19 & COC

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR & THE HONOURABLE MR. JUSTICE SHAJI P.CHALY THURSDAY, THE 18TH

DAY OF NOVEMBER 2021 / 27TH KARTHIKA, WP(C) NO. 5166 OF 2019 PETITIONER: ALBIN MATHEW, AGED 27 YEARS,OZHACKAL HOUSE, IDUKKI COLONY P.O., IDUKKI-685 602. BY ADVS. PHILIP J.VETTICKATTU SMT.ANEY PAUL RESPONDENTS: 1 THE STATE OF KERALA, REPRESENTED BY ITS SECRETARY, HEALTH AND FAMILY WELFARE DEPARTMENT, GOVERNMENT SECRETARIAT,TRIVANDRUM-695 001. 2 THE DISTRICT COLLECTOR IDUKKI, COLLECTORATE,IDUKKI-685 584. 3 THE DISTRICT MEDICAL OFFICER OF HEALTH, OFFICE OF THE DISTRICT MEDICAL OFFICER,IDUKKI-685 561. 4 IDUKKI DISTRICT PANCHAYAT OFFICE OF THE IDUKKI DISTRICT PANCHAYAT, IDUKKI-685 561, REPRESENTED BY ITS SECRETARY. 5 THE SECRETARY VAZHATHOPPU GRAMA PANCHAYAT, VAZHATHOPPU, IDUKKI DISTRICT, IDUKKI-685 561. 6 THE HEALTH INSPECTOR PRIMARY HEALTH CENTRE, VAZHATHOPPU, IDUKKI DISTRICT-685 602. 7 THE ENVIRONMENTAL ENGINEER POLLUTION CONTROL BOARD, THODUPUZHA, IDUKKI-685 584.

8 JOY SEBASTIAN PROPRIETOR, J.K. DIAGNOSTIC CENTRE, CHERUTHONI, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI DISTRICT-685 602. 9 JABBAR M.M., EDAKKUDIYIL, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI DISTRICT-685 602. 10 JOSE T.J. PROPRIETOR BHARATH DIAGNOSTIC CENTRE. CHERUTHONI, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI-685 602. 11 ALIYAMMA C.T@ALEES THEKKEL, IDUKKI COLONY P.O., CHERUTHONI, IDUKKI VILLAGE, IDUKKI DISTRICT-685 602.

BY ADVS. SRI.UNNIKRISHNAN V.ALAPATT, SC, IDUKKI DISTRICT PANCHAYATH SRI.JIMMY GEORGE (THADATHIL) SRI. T.NAVEEN SC, KERALA STATE POLLUTION CONTROL BOARD, SMT.V.GEETHA POTTI SRI.BABY MATHEW SRI.JIBY G.J. SRI.JOSEPH KODIANTHARA (SR.) JOICE GEORGE SR.GP. SRI.V.TEKCHAND THIS WRIT PETITION (CIVIL) HAVING COME UP FOR ADMISSION ON 18.11.2021 ALONG WITH WPC 19741/2018 AND COC 672/2019, THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING:

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR & THE HONOURABLE MR. JUSTICE SHAJI P.CHALY THURSDAY, THE 18TH DAY OF NOVEMBER 2021 / 27TH KARTHIKA, CON.CASE(C) NO. 672 OF 2019 AGAINST THE ORDER IN WP(C) 19741/2018 OF HIGH COURT OF KERALA PETITIONER: ANILKUMAR G., AGED 42 YEARS, S/O. GANGADHARAN (LATE), ANACKANATTU HOUSE, MANIYARANKUDY P.O, IDUKKI 685 602. BY ADVS. SRI.J.JULIAN XAVIER SRI.FIROZ K.ROBIN RESPONDENTS: 1 PRIYA.N, PRESENTLY WORKING AS DISTRICT MEDICAL OFFICER, (AGE AND FATHERS NAME NOT KNOWN TO THIS PETITIONER) OFFICE OF THE DISTRICT MEDICAL OFFICER, IDUKKI 685 561. 2 CHELLAPPAN P.T, PRESENTLY WORKING AS SECRETARY, VAZHATHOPE GRAMA PANCHAYAT, (AGE AND FATHERS NAME NOT KNOWN TO THIS PETITIONER) VAZHATHOPE, IDUKKI DISTRICT 685 602. 3 JOY SEBASTIAN, PROPRIETOR, J.K DIAGNOSTIC CENTRE, (AGE AND FATHERS NAME NOT KNOWN TO THIS PETITIONER) CHERUTHONI, IDUKKI COLONY P.O, CHERUTHONI, IDUKKI DISTRICT. BY ADV SRI.JIMMY GEORGE (THADATHIL) SRI.V.TEKCHAND, SR. GP SMT.V.GEETHA POTTI SRI.T.V.GEORGE. THIS CONTEMPT OF COURT CASE (CIVIL) HAVING COME UP FOR ADMISSION ON 18.11.2021 ALONG WITH WPC 19741/2018 & FOLLOWING: C.R.

JUDGMENT

Dated this the 18th day of November, 2021 [W.P.(C) Nos.19741 of 2018 & 5166 of 2019 & Cont. Case (C) No.672 of 2019] S.Manikumar, C.J. In W.P.(C)No.19741 of 2018, the petitioner has sought for the following relief: i. To issue a writ of mandamus or any other appropriate writ, order or direction directing the respondents 2 and 5 not to permit the respondents 7 to 9 to conduct clinical laboratories in the bunks taken on lease from the 3rd respondent, without providing sufficient facilities as mandated in Ext.P1.

2. Short facts leading to the filing of W.P.(C)No.19741 of

2018 are as hereunder: Petitioner is approaching this Hon'ble Court in this writ petition in public interest with a grievance that the bunks given in auction for conducting small business concern are now converted into Clinical Laboratories

without having necessary infrastructure facilities as mandated by Indian Council of Medical Research, New Delhi. The Government of Kerala have issued Kerala Clinical Establishment (Registration and Regulation) Bill, 2017 with an objective of improvement of public health in prescribing minimum standards for different categories of clinical establishments to ensure the provision of proper quality health care by the clinical establishments which is now under the process of getting assent from the Governor. The 3rd respondent District Panchayat auctioned different bunks on the side of the entrance of Idukki Medical College for conducting small bunks for business purposes. Respondents 7 to 9, after auctioning the bunks, started clinical laboratories without having any facilities against which the petitioner filed various complaints before the respondents 1 to 4 and pursuant to which the respondents 2 and 5 directed the respondents 7 to 9 to close down the clinical laboratories in the bunks which are being conducted without any facilities as mandated in Ext.P1. However it is reliably learned that steps are being taken to reopen the clinical laboratories in the bunks without having the facilities mandated in Ext.P1 on extraneous pressure.

3. In W.P.(C)No.5166 of 2019, the petitioner has sought for the following reliefs:

1. Issue a writ of Mandamus or any other appropriate order, writ or direction directing the respondents 1 to 5 to take immediate steps to stop the functioning of the blood collection centres and activities conducted by respondents 8 to 11 in their respective bunks auctioned by them from the 4th respondent;

2. Issue a writ of Mandamus or any other appropriate

order, writ or direction directing the 5th respondent to cancel the licenses issued to respondents 8 to 11 and not to grant/renew the same for conducting any blood collection centres or laboratories in their respective bunks, where they are conducting blood collection certres;

3. Issue a writ of Mandamus or any other appropriate

order, writ or direction directing the respondents 1 to 5 not to permit respondents 8 to 11 to collect human specimen including blood without having facilities as

contemplated under Act, 2018 and registration under the provisions of the said Act.

4. Short facts leading to the filing of W.P.(C)No.5166 of

2019 are as hereunder: The petitioner is highly aggrieved by the callous and lethargic attitude of the respondents in considering and taking appropriate action against the illegal blood and human specimen collection centres conducted by the respondents on road side bunks. Even the recent disturbing press reports about spread of HIV through blood transmission have not evoked any response in the official respondents to react to the cause exposed by the petitioner. Further the Government of Kerala has recently enacted the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (hereinafter be referred to as Act, 2018 for brevity). The provisions of the Act 2018 make it clear that road side bunks used for collecting blood and body specimen are impermissible. However, the official respondents, in spite of being alerted about the continuation of such illegal conducting of body specimen collection in road side bunks are not taking any action presumably because of the influence and pressure exerted by the party respondents. The continuation of such illegal practice is dangerous to the health of the general public and liable to be interfered with.

5. Considering the averments and the material on record, a Division Bench of this court, on 14.06.2018 in W.P. (C)No.19741 of 2018, has passed the following order:

The concern of the petitioner in this PIL is the functioning of clinical laboratories in front of the Idukki Medical College in small roadside bunks, without proper toilets and other hygienic facilities.

2. The learned counsel Sri.J.Julian Xavier appearing

> for the petitioner refers to the auction notice dated 26.4.2018, Ext.P2(a), of the District Office, Idukki to show that the bunk No.8 covered by the auction was available only for conducting small business like tea stall, stationery, fruit stall, STD booth, barber shop etc. But, the bunk No.8 and

two similar roadside bunks are now being utilised as clinical laboratories without adherence to the Ext.P1 guidelines, issued by the Indian Council of Medical Research. The petitioner has also voiced concern about the pollution and other health hazards, emanating from the said laboratories.

3. In view of the above, urgent notice by speed post

returnable in three weeks be issued to the private respondents, respondents 7 to 9. Standing Counsel Sri.Unnikrishnan V. Alapatt accepts notice for the Idukki District Panchayat, the third respondent. Notice for the State Authorities, respondents 1, 2 and 5 is accepted by the learned Government Pleader Sri.V.Tek Chand. The

learned Standing Counsel Sri.T.Naveen accepts notice for the Pollution Control Board, the 6th respondent. We are told that at present the three clinical laboratories of private respondents are not functioning and if that be the position, status quo as on today, shall be maintained.

6. Subsequently, alleging non-compliance of the order

dated 14.06.2018, petitioner in W.P.(C)No.19741 of 2018 has filed Contempt Case (C)No.672 of 2019.

7. On 8.4.2019, after considering the submissions of the parties in the writ petitions as well as contempt petition, a Division Bench of this court ordered thus:

Heard the learned counsel for the parties particularly, the learned Senior Counsel Sri.Joseph Kodianthara appearing for J.K. Diagnostic Centre and New Modern Laboratory and the learned counsel Sri.Baby Mathew appearing for Bharath Diagnostic Centre, who are reportedly operating clinical laboratories on the roadside bunks, near the Idukki Hospital. The operators contend that the bunks are operating only as specimen collection centres and not as laboratories.

2. In the above context, it is seen from the recent communication dated 15.3.2019 (Ext.P7) in the W.P. (C)No.5166 of 2019 that the Environmental Engineer has

> conducted inspection on 13.3.2019 on the functioning of the New Modern, Bharath and J.K. Lab collection centres near the Idukki Medical College and has confirmed that these centres do not have any facilities, to dispose of the solid/liquid wastes or bio medical wastes. Accordingly, they have been asked to stop functioning.

3. In view of above, it is made clear that the

concerned collection centres i.e. New Modern, Bharath and J.K. Lab shall cease to conduct their collection operation until they secure the necessary clearance from the Kerala State Pollution Control Board. It is ordered accordingly as an interim measure.

8. Mr.Joy Sebastian, Proprietor, J.K. Diagnostic Centre

and Mr.Jabbar A.M., New Modern Diagnostic Centre, respondent No.7 and additional respondent No.10, have filed a counter affidavit dated 19.12.2018 and Mrs.Aliamma C.T., additional respondent No.11, has filed a counter affidavit dated 2.4.2019, opposing the prayers sought for.

9. On this day, when the matter came up for hearing, on

the basis of the counter affidavit dated 29.10.2021 filed by the District Medical Officer, Idukki (respondent No.2), Mr.V.Tekchand, learned Senior Government Pleader submitted that pursuant to the directions of this court, an inspection was conducted on 01.06.2018 in the matter of conducting clinical laboratories in the bunks and in the collection centres situated near to Idukki Medical College, conducted by respondents 7 to 11 and certain shortcomings were noticed.

10. Again an inspection was conducted on 23.11.2021.

Following the inspections and defects noticed, the District Medical Officer, Idukki (respondent No.2) suspended the functioning of clinical laboratories/collection

centres until the defects were rectified. Subsequently, the centres were also closed. In support of the above contention, Mr.V.Tekchand, learned Senior Government Pleader relied on the averments in paragraphs 2 to 4 of the counter affidavit dated 29.10.2021 filed by the District Medical Officer, Idukki and the annexures filed thereto.

11. Relevant paragraphs of the counter affidavit dated 29.10.2021 are reproduced: 2. It is respectfully submitted that the above Writ Petition is filed for issuance of writ of Mandamus or any

> other appropriate writ order or direction directing the respondents 2 and 5 not to permit respondents 7 to 9 to conduct clinical laboratories in the bunk taken on lease from the 3rd respondent without providing sufficient facilities as mandated in Exhibit P1. It is respectfully submitted that the petitioner submitted Exhibit P5 complaint to this respondent against the collection centres of clinical laboratories situated near to Idukki Medical College. On the basis of the complaint received, an enquiry was conducted on 01.06.2018, In the enquiry, it was revealed that the laboratory conducted by the respondents 9 & 11 are collecting sample collection in the bunk and that a separate area is used for the Investigation purpose of the sample so collected. The other two centres run by respondents 7, 8 & 10 are used only as collection centres. In the inspection certain defects were noticed and therefore notices were issued to the concerned owners to close down the units immediately. Thereupon, the laboratories have stopped functioning from 01 06.2018. By applications dated 04.06.2018 and 05.06.2018 the proprietors of the clinical laboratory submitted applications to this respondent informing that the defects pointed out in the notice are rectified and sought permission to re open the lab after necessary verification. Based on the applications an inspection was carried out on 06.06.2018 It was noted that the defects pointed out earlier were rectified. Thereupon, orders were issued allowing opening of the lab centres subject to the conditions specified in the order. Based on the permissions so granted from

08.06.2018, the lab

centres started functioning.

3. It is respectfully submitted that another inspection

was carried out on 23.10.2021. In the inspection, it was found in all the laboratories that the lab technicians posted and present are not qualified as stipulated by the State. Further the bunk does not have proper toilet facilities, privacy, drinking water facilities, resting area and cleanliness. Further it was noticed that the proprietors of the laboratory have not ensured protective devices such as gloves for the staff. In addition to the above, it was seen that the sample collection test tubes were dusty and kept in open places. It was also found that the laboratories did not have proper liquid waste management system and the wastes are diverted to an open place via pipes. Bio medical waste were kept in the bunk up to the time of collection from the IMAGE. The premises of the laboratories were seen having growth of weeds which may in turn result in the flourishing of rodents and reptiles which may prove to be harmful to the public.

4. In the above circumstances, notices dated

27.10.2021 were issued to respondents 7, 8 & 10 and 9 &11 to immediately close their clinical lab collection centre. True copy of the notices issued to the aforestated respondents are produced herewith and marked as Exhibit R2(a), Exhibit R2(b) and Exhibit R2(c) respectively. A copy of the aforesaid notices has been forwarded to the Secretary, Grama Panchayath. Vazhathopp for initiating necessary action. Under the circumstance, this Honourable Count may be pleased to find that this respondent had taken prompt

action against a clinical lab collection centres mentioned in the Writ Petition.

12. Annexures R2(a), R2(b) and R2(c) are the orders of

suspension of functioning of clinical laboratories/collection centres until rectification of the defects. As the orders of suspension dated 27.10.2021 issued by the District Medical Officer, Idukki (respondent No.2) to Smt.Raji E.R. and Sri.Jabbar A.M.; Sri.Jose T.J. and Smt.Aliamma C.T. and Sri.Joy Sebastian are similar in nature, suffice to incorporate the suspension order dated 27.10.2021 issued to Smt.Raji E.R. and Sri.Jabbar A.M., Annexure R2(a) and the same is extracted:

No.C4-4200/19 (1) District Medical Office (Health), Idukki Date 27.10.2021 Email:dmohik@gmail.com From, District Medical Officer (H) Idukki To, Smt. Raji E.R. & Sri. Jabbar A.M. Newmodem Laboratory/collection center Cheruthoni, Near Idukki Medical College. Sir, Subject: Suspension of the functioning of Clinical laboratories/collection center until rectification of the defects - regarding. Reference:- 1) Case No. WPC NO 19741/2018 under consideration of Hon'ble high court. 2) Inspection conducted from this office on 23.10.2021. We have inspected the J.K. diagnostic & collection center and premises functioning in a bunk within an area of 52.5 sq ft located on the left side of Idukki medical college road owned by you on 23.10.2021 at 11 a.m. The following defects were found during the inspection:

1. The bunk has no requisite space to function as a clinical laboratory/ collection center.

2. The clinical laboratory/collection center has no sufficient space for resting of the patient and bystanders.

3. The lab does not ensure sufficient drinking water facilities.

4. The lab has not provided toilet facilities.

5. The premises of the lab collection center have seen weeds and it may lead to the growth of rodents and reptiles.

6. The laboratory collection center has diverted the waste water to open space.

7. The biomedical waste is kept in the bunk up to the collection time from the IMAGE.

8. The test tubes and other equipment openly kept in the bunk were seen dusty and unhygienic.

9. The lab/collection has not ensured sufficient personnel protective devices like gloves for employees.

10. The employee who has been posted in the lab/collection center has not requested qualification as per the state government.

11. The lab/collection center has not provided privacy measures. For the above reasons, the functioning of the laboratory/clinical center should be closed till further order. Yours sincerely District Medical Officer (Health)

13. In the light of the implementation of the directions

issued by this court and taking note of the submission of the suspension of functioning of the clinical laboratories/ collection centres, Mr.Julian Xavier, learned counsel for the petitioner submitted that recording the above, writ petition can be closed.

14. Material on record discloses that insofar as

conducting of clinical laboratories, certain Guidelines have been issued by the Indian Council of Medical Research, New Delhi. Inasmuch as the reliefs pertain to conduct of clinical laboratories/collection centres, we are of the view that the abovesaid Guidelines have to be strictly implemented.

15. For brevity, Guidelines for Good Clinical Laboratory Practices (GCLP) issued by the Indian Council of Medical Research, New Delhi, are extracted: 1.0 INTRODUCTION

> Laboratory services are an integral part of disease diagnosis, treatment, monitoring response to treatment, disease surveillance programmes and

clinical research. The World Development Report 1993, regarded provision of Essential Health Technology as an important ingredient of Essential Clinical Services. Use of diagnostic techniques aid early diagnosis enabling appropriate and prompt intervention thereby reducing overall disease burden and promoting health. All laboratories are not equipped with facilities for carrying out complex investigations. The structure and function of a clinical laboratory varies according to the level of health care facility. Peripheral laboratories carry out simple tests like urine analysis and haemoglobin estimation whereas higher centers are equipped with sophisticated technology and trained manpower to carry out complex investigations. Establishing a network between peripheral and higher laboratories allows collection of specimen at periphery and their storage and transport for testing at higher centers and communicating report to the peripheral center efficiently without actually having to transfer the patient. In the event of patient transfer, the higher centers do not need to repeat investigations carried out at the peripheral health center, thereby saving crucial time as well as cost and providing continuity in patient care. Networking between laboratories is also essential in disease surveillance programmes and outbreak investigations in order to obtain quick and reliable results. The expert committee on Revamping of Public Health System identified the surveillance and control of diseases as an important function of public health system. This formed the conceptual framework of Integrated Disease Surveillance Programme (IDSP) which was started in 2004 in a phased manner. The key components of IDSP are coordination and decentralization of disease surveillance activities, improvement of laboratory support and strengthening data quality. Inclusion of private laboratories to act as sentinel sites and improve community participation are some other

important features. The Reproductive and Child Health - II programme of Government of India in 2005, indicated the need for developing public-private partnership in health care including outsourcing of health care,

laboratory services and others. It outlines the need for accreditation of service quality including protocols for quality assurance and certification. In India, medical laboratories can volunteer for accreditation of one or more services offered by them. The National Accreditation Board for Testing and Calibration Laboratories (NABL) has been providing accreditation services to medical laboratories since 1998 and is currently following ISO 15189; 2007 standards. In biomedical research too, achieving a set standard of quality produces credible results and allows comparison between studies carried out at different institutes nationally and internationally. This saves enormous time, money and resources and prevents duplication of research work. The International Conference on Harmonization (ICH) provided Good Clinical Practices (GCP) Guidelines which describe standards to be followed by researchers while designing, conducting and reporting trials involving human participants. Realizing the rapid pace, wide spectrum and potential for clinical research in our country, the Indian Council of Medical Research (ICMR) launched the Ethical Guidelines for Biomedical Research on Human Subjects in 2000 (revised in 2006) and Central Drugs Standard Control Organisation (CDSCO) released the Indian Good Clinical Practices (GCP)

guidelines in 2002 to guide biomedical research in the

country. To harmonize practices and generate mutually acceptable data for non-clinical health and environmental safety studies the Organization for Economic Cooperation and Development (OECD) evolved Good Laboratory Practice

(GLP) guidelines. India is a signatory to OECD and National

GLP Compliance Monitoring Authority established in the year 2002 by the Department of Science & Technology, Government of India, provides GLP compliance certification to the test facilities involved in conducting safety studies on chemicals (viz. industrial chemicals, pharmaceuticals, veterinary drugs, pesticides, cosmetic products, food products, feed

additives, etc). To ensure reliability of data quality, WHO/TDR (Research and Training in Tropical Diseases) has developed good practice guidelines for laboratories involved in clinical trials. However, standards have not yet been developed in India for this purpose. The proposed ICMR guidelines for Good Clinical Laboratory Practices (GCLP) aim to elucidate step wise procedures which

should be followed by laboratories to strengthen the quality of test results. These guidelines should be adopted by all ICMR laboratories engaged in research as well as patient care. ICMR carries out research activities through its own institutes as well as through approved research centers in the public and private health systems. It also provides financial support to projects submitted by individual researchers and institutes. Adopting these guidelines will lead to generation of uniformly acceptable and good quality laboratory data. Subsequently, a checklist will be prepared to monitor these laboratories for compliance with these guidelines.

2.0 SCOPE

Good Clinical Laboratory Practices should be used by all laboratories where tests are done on biological specimens for diagnosis, patient care, disease control and research such as: Microbiology & Serology Hematology & Blood Banking Molecular Biology and Molecular Pathology Clinical Pathology Clinical Biochemistry Immunology (Immunohematology and Immunobiochemistry) Histopathology/Pathology and Cytology.

3.0 LEVELS OF LABORATORIES

In India, the laboratory services are integrated with the 3-tier public health system at the primary, secondary and tertiary levels. Besides these, there are Reference Laboratories, Research Laboratories and

Specific Disease Reference Laboratories to provide services for complex and special tests. The private sector provides laboratory support at all levels of health care both in rural and urban areas. Each laboratory should identify the scope, functions and the capacity of the services offered by it and appropriate infrastructure with requisite biosafety measures should be planned. Qualified and trained staff should be employed with periodic up-gradation of their skills.

3.1 Primary Level Simple laboratory tests such as haemoglobin estimation and urine examination for albumin and sugar are carried out at Primary Health Centers (PHCs) and Urban Health Centers (UHCs) by laboratory technicians. Most PHCs and UHCs also have microscopy facilities and trained technicians for

examining blood smear for malarial parasite and sputum for acid-fast bacilli (AFB) and a cold chain system. The Community Health Centers (CHCs) receive referrals from PHCs and the laboratory technicians are trained and equipped to handle additional laboratory investigations for the management of medical and surgical emergencies and making etiological diagnosis of RTIs/STIs. Facilities for screening of G6PD deficiency, sickle cell anaemia and thalassemia are also available for vulnerable communities. Under IDSP, training will be provided for diagnosis of typhoid using kits, detection of chlorination levels and fecal contamination in water samples.

3.2 Secondary level The district hospitals have facilities and manpower for carrying out pathology, clinical pathology, biochemistry, serology, and microbiological investigations. They also carry out tests of water quality and receive referrals from primary level facilities. The laboratory staff includes pathologists, microbiologists, cytotechnicians, laboratory technicians, blood bank technicians and laboratory attendants.

3.3 Tertiary level The medical college hospitals and non-teaching large hospitals are equipped with sophisticated diagnostic and investigative facilities to provide

tertiary level health care. These hospitals receive referrals from the primary as well as the secondary levels.

3.4 Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories The Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories provide services in a specialized field or area of importance. These may be located in a medical college, research institution or a private institution. They set and should maintain high standards of quality in one or more particular area and therefore receive referrals specific to that field. They also offer consultancy, standardize diagnostic tests and carry out training pertaining to that specific area.

4.0 INFRASTRUCTURE Infrastructure of laboratories should be planned according to the services provided by the laboratory. The basic infrastructure facilities include:

Reception room/area where requisition forms are received and reports disbursed Specimen collection room/area, toilets, privacy for special purposes eg. semen collection, facilities for disabled persons, toilet for staff Quality water supply for analytical purpose Uninterrupted power supply Analytical work area Specimen/Sample/slide storage facility including cold storage where applicable Record room/area Facility for cleaning of glassware, sterilization /disinfection Waste disposal facility including biomedical wastes Fire-safety equipment Ventilation, climate control and lighting arrangements Separate room/area for meetings/administrative work Separate facilities/area for staff for hand washing, eating and storing food, drinks etc. Communication facility with referral centers Transport of specimen/samples to referral centers Additional infrastructure facilities may be added for special tasks as and when needed.

5.0 PERSONNEL, TRAINING AND DEVELOPMENT

Each laboratory should designate a Head of the laboratory who should be overall in-charge of the daily functioning of the laboratory including administration. A Quality Manager should be designated for monitoring and maintaining of day- to-day quality management system. The qualifications and experience of the staff outlined in NABL document 112 (2007) should be followed unless specified by the health care providers. The strength of staff employed should be appropriate to the level of facility and the workload. The roles and responsibilities of the staff should be clearly outlined. The staff should also understand the nature of work assigned to them and must be capable of performing the tasks independently beyond routine working hours if the need arises. A programme for technical training and updating of skills on a regular basis should be in place. The laboratory management should be committed for providing continuing professional development and training opportunities to staff. Action plan for improvement in the laboratory should be determined and revised according to the feedback received

from previous trainings and experiences. Laboratory should organize or conduct periodic staff evaluation, preferably once a year; frequency and method of evaluation should be decided by the laboratory. The laboratory should maintain a personal file of all the technical and nontechnical staff employed. Personal file should contain all information on: Personal bio-data including educational qualification and experience Copy of degree/diploma and registration with state authority if applicable Copy of appointment letter Duly verified health information (physical fitness including color blindness, immunizations received etc.) prepared at the time of employment and its regular updates Performance appraisal Training certificates, awards/recognition received Disciplinary action if any taken by the management Reference letter from previous employer if applicable

6.0 EQUIPMENT

Each laboratory should prepare an exhaustive list of equipment and consumables required and available for general functioning of the laboratory and specialized equipment for special tests. Laboratory equipment should be of adequate capacity to meet work load requirement. Equipment should be suitably located in the laboratory so as to allow accessibility and sequential utilization thus minimizing the need for frequent movement of specimens or reagents. All equipment should be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment should be done. An equipment log book should be maintained for all major equipment. Laboratories should maintain necessary instructions for operation and maintenance of equipment in the form of Standard Operating Procedures (SOPs). A copy of SOP should be readily available. Maintenance contracts including warranty cards, telephone numbers of staff to be contacted in case of equipment malfunction should be kept safely. User manual should be available readily for reference. The staff should be aware of trouble shooting measures to be adopted for preventing equipment malfunction. A format of the equipment log book provided in Annexure 1 can be used.

New equipment should be calibrated and validated before routine use. AMR (Analytical Measurement range) should be verified, manufacturer can be consulted for verification and selection of range. Periodic performance check/calibration check for all equipment should be done using reference standard/reference material. The frequency of performance check should be based on the day-to-day performance of the equipment. Equipment performance should be verified from Internal Quality Control results and External Quality Assessment results. Outlier parameter trend analysis record should be maintained in respect of its effect on the equipment. All analytical equipment should be calibrated and calibration certificate provided by equipment company. Non-analytical equipment such as pipette, thermometer, weighing balance and centrifuge should be calibrated by accredited calibration laboratory

or done in-house with traceability to National Physical Laboratory (NPL). For in-house calibration, laboratories should use : Calibrated tachometer - for centrifuge Calibrated digital temperature sensor - for checking temperature of refrigerator, incubator etc. Calibrated glass thermometer- for temperature checking of oven, water bath etc. Calibrated weights - for balance National Institute of Science and Technology (NIST) buffer - for pH meter. Standard buffer solutions bought from reputed manufacturers with certifiable traceability can be used as alternative. Equipment measuring pressure, temperature, humidity etc. should be checked by using suitable reference standards.

7.0 REAGENTS AND MATERIALS

Standard reagents of certified quality must be used for the purpose of analysis. The batch number of reagents must be recorded. The quality of the reagent viz. Analar grade, HPLC grade, etc. to be used for in-house procedures should be defined in SOP The reagents, chemicals and consumables should be stored under appropriate environmental conditions. Quality of newly purchased reagents should be validated against suitable control/reference material prior to use. Validation data should be properly documented. In-house prepared reagents should also be checked periodically for

stability and a record of the same should be maintained. Reagent label should contain name of reagent, concentration, date of preparation/opening, date of expiry, storage conditions and warnings eg. 'do not use if solution is turbid' where applicable. When individual bottles are small, this information can be recorded in a goods received ledger. Microbiology laboratories should check activity/potency of each lot of antibiotic sensitivity discs before using and at least weekly thereafter with reference strains. Other microbiological consumables such as strips etc. used for identification should be checked against reference strains. Laboratories testing microbiology specimens should check the quality of

media by using appropriate reference strain and pH of the media. All batches of culture containers should be checked for sterility before issuing to patients for collection of specimen. Water quality should be checked for its grade and presence of interference elements. Reagent grade water according to IS1070 : 1992 of Bureau of Indian Standards (BIS) should be used for testing.

8.0 SPECIMEN COLLECTION

Specimen collection is the first phase of interaction between the patient and the laboratory. Appropriate counselling should be done before specimen collection and consent taken whenever needed. Attention should be paid to patient's sensibilities during the entire process. Any error in specimen collection can lead to erroneous results. It is therefore considered an important step of good clinical laboratory practice and is referred to as "preanalytic control". Specimen collection can be done at the patient's bedside, in the laboratory or in the field. Trained manpower/phlebotomist should be employed for specimen collection. Other staff such as doctors, nurses and others who are involved in specimen collection should also be trained periodically. Laboratory should have a "primary specimen collection manual", containing information on patient preparation before specimen collection (if any), exact methodology of specimen collection, labelling, handling, transportation and storage of the specimens. In addition, the laboratory should provide adequate and appropriate information/instructions to patients wherever necessary. All preanalytical factors that may influence the test results should be identified. The

manual should include guidelines on specimen collection including preservation for histopathological examination. These manuals should be available for reference and should be used for training of staff engaged in specimen collection. Specimen should be secured properly so that there is no leakage, spillage or contamination. A Biohazard symbol should be

used on the containers during transportation. Appropriate specimen transportation kit (such as use of dry ice, etc.) to be used wherever required. Specimen should be sent to the laboratory along with the requisition form.

9.0 REQUISITION FORM

The requisition form should be completed by the doctor requesting the tests and sent along with the specimen/patient to the laboratory. It should contain the patient's identity, age, location, date of specimen collection and the investigations requested. The referring doctor should be encouraged to mention the provisional or working diagnosis and relevant clinical and treatment history in the space provided (Annexure 2).

10.0 ACCESSION LIST

Accession list is a record of all the specimens received by the laboratory for analysis and is prepared by the laboratory at the time of specimen receipt (Annexure 3). It records the patient's identity including name, age, sex, location in the hospital/ medical facility, name of referring physician, investigations requested, date and time of receipt of specimen and condition of the specimen at receipt. The laboratory assigns a unique laboratory number to register each specimen received, which can be used to trace the specimen in the laboratory. The test results and remarks if any are also entered in the accession list. In laboratories handling a very large number of specimens, the accession list may be computer generated and the condition of specimen at receipt may not be recorded unless it has been rejected.

11.0 WORKSHEET Worksheet is essentially a form provided to the analyst along with the specimen (Annexure 4). The following details should be recorded on the worksheet: Date of analysis

Condition of the specimen before starting analysis (should be entered in the laboratory notes) Findings and result Name and signature of the analyst (In case of electronically generated and maintained worksheets, appropriate control, validation and access procedures should be built in the system) Laboratory number assigned to the specimen should be mentioned in the worksheet before sending the specimen to the analyst. The specimen should be analyzed according to the plan mentioned in the SOP. Any deviations from the analysis plan should be mentioned giving reasons. Wherever applicable the laboratories can use requisition form cum worksheet (Annexure 5) instead of two separate forms. However, laboratories using electronic transmission of patients' details and test results may not require individual worksheets.

12.0 REPORTING TEST RESULTS

Test results approved and signed by the designated authority should be made available to authorized person(s) only. Results should be reported clearly, without any errors, specifying measurement procedure where appropriate and units of measurement as recommended by professional societies such as International Council for Standardization in Haematology, International Society of Haematology & International Federation of Clinical Chemistry and Laboratory Medicine. A format for reporting results is given in Annexure 6.

13.0 SPECIMEN REJECTION RECORD

Laboratories should maintain a record of specimens which were rejected prior to analysis. Rejection statistics (eg. number of hemolyzed specimen etc.) along with reason for rejection and person responsible for rejection should be maintained (Annexure 7). Specimen rejection statistics can be used by laboratories to identify the need and areas for staff training. For example, if specimen contamination is detected, the containers should be checked for sterility prior to collection as well as specimen handling

procedure. This information should be shared with the medical, nursing and other staff engaged in specimen collection and transportation.

14.0 DATA MANAGEMENT

Laboratory data management includes recording details of the patient, findings of analysis, reporting of results and archiving the data for future reference. Recording data allows smooth functioning of the internal quality control measures, internal audit and external quality assessment. From the point of view of management, absence of record implies that the work was never done. The format of recording and reporting results should be described in the Standard Operating Procedures (SOPs). Data entry should begin as soon as registration number is assigned to the specimen. Further entries should be made in the accession list and worksheet. The final report should be recorded after approval/signature of the designated authority. All auto analyzers should be connected with printer and uninterrupted power supply (UPS). If printing option is not available or semi auto analyzers are used, laboratory should maintain manual raw test data counter-checked by two persons. The laboratory should maintain raw test data preferably for one month in noneditable format or signed printed copy. Procedure for adequate data protection and security including data editing and deleting should be developed and maintained by the laboratory. Authorization for amendment procedure should be specified in the SOP. Thelaboratory should also record reason for editing or deleting data. Facilities sending reports electronically should include electronic signature of the authorized signatory. Laboratories should be able to provide critical information required by a physician on telephone eg. frozen section biopsy report is required while operating a patient with suspicion of cancer or growth of a particular organism in culture can aid in early diagnosis and treatment.

15.0 STANDARD OPERATING PROCEDURE (SOP)

SOP is a document, which contains detailed, written instructions describing the stepwise process and technique of performing a test or procedure in the laboratory. SOP helps to ensure uniformity, consistency and control over the processes carried out. It ensures that the procedures are done in exactly the same way each time irrespective of the operator.

SOP should contain information on who can perform the test, their qualification and training, how to carry out the test including pre-analytical, analytical and post-analytical stages of test/procedure, laboratory conditions required for the test/ procedure, routine care and maintenance of equipment, precautions and safety instructions, trouble shooting measures, waste disposal and linkage with reference laboratories. SOP should be simple and written in an easy to understand language. The procedure described in the SOP must be followed exactly by all staff members to ensure high quality results. It should be titled along with version number, dated and signed by an authorized person and updated regularly. It is important for the SOP document to be readily available in the working area and is therefore also referred to as 'laboratory bench work manual'. SOPs are controlled documents and can be changed only with approval of the laboratory quality manager and/or Head of the laboratory.

Benefits of EQA Assesses the overall performance of laboratory Establishes inter-laboratory comparison Serves as an early warning system for problems Identifies systematic kit problems Provides objective evidence of laboratory quality Indicates areas towards which efforts need to be directed for improvement of quality of results Identifies training needs

22.0 INTERNAL AUDIT

Audit is a process of critical review of the functioning and evaluation of services. Internal audit is the systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the specific criteria are complied with. Internal audit can be effectively carried out by examining documents, specimens, equipment, environmental conditions, examination procedures and personnel competence. Effective internal audit will identify the problems and weak points in the system and suggest remedial measures.

23.0 SUMMARY OF QAP ACTIVITIES

Establish QC Policy & QC Procedure Secure QC material supply for several months, preferably for one year with same lot number for both normal & abnormal QC Construct LJ charts and plot daily QC values Scan LJ charts for trends and shifts Define "out-of control limits" and corrective actions Participate in EQA programmes Evaluate IQC & EQA reports once a month towards method / analyzer modifications Evaluate the whole QC programme once a year for its effectiveness, cost and areas needing attention.

16. Government of Kerala represented by the Health

and Family Welfare Department and the official respondents in writ petitions, are directed to implement the Guidelines in letter and spirit. Secretary to the Government, Health and Family Welfare Department, Thiruvananthapuram (respondent No.1 in both the writ petitions), is directed to issue appropriate instructions to all concerned for effective implementation of the Guidelines.

17. Concerned District Collectors, District Medical

Officers and Secretaries of local bodies are directed to implement the Guidelines and the further instructions issued by the Secretary, Health and Family Welfare Department, Thiruvananthapuram (respondent No.1 in both the writ petitions).

18. Though Ms.Geetha Potti, learned counsel for

respondents 7 to 11, submitted that defects as pointed out by the District Medical Officer, Idukki (respondent No.2), have been rectified, we are not inclined to issue any directions as it is for the respondents to approach the competent authority for appropriate directions.

19. In the light of the above, writ petitions are disposed

of with directions stated supra. There is no willful and intentional violation of the directions in the interim order dated 14.06.2018 in W.P. (C)No.19741 of 2018. Contempt petition is accordingly closed. Pending interlocutory applications, if any, shall stand closed. Sd/- S.Manikumar Chief Justice Sd/- Shaji P.Chaly Judge vpv APPENDIX OF WP(C) 19741/2018 PETITIONER EXHIBITS EXHIBIT P1 TRUE COPY OF THE RELEVANT EXTRACT OF

GUIDELINES FOR GOOD CLINICAL LABORATORY

PRACTICES (GCLP) ISSUED BY THE INDIAN COUNCIL OF MEDICAL RESEARCH, NEW DELHI. EXHIBIT P2 TRUE COPY OF ONE TENDER NOTIFICATION DATED 26.04.2018 ISSUED BY THE 3RD RESPONDENT. EXHIBIT P2(A) ENGLISH TRANSLATION OF EXT.P2. EXHIBIT P3 TRUE COPY OF THE PHOTOS SHOWING THE BUNKS WHICH IS CONVERTED AS CLINICAL LABORATORIES BY THE RESPONDENTS 7 TO 9. EXHIBIT P4 TRUE COPY OF THE COMPLAINT DATED NIL SUBMITTED BEFORE THE 1ST RESPONDENT. EXHIBIT P4(A) ENGLISH TRANSLATION OF EXT. P4. EXHIBIT P4(B) COPY OF THE AD CARD SIGNED BY THE 1ST RESPONDENT DATED 19.05.2018. EXHIBIT P5 TRUE COPY OF THE COMPLAINT DATED NIL SUBMITTED BEFORE THE 2ND RESPONDENT. EXHIBIT P5(A) ENGLISH TRANSLATION OF EXT.P5. EXHIBIT P6 TRUE COPY OF THE PAPER NEWS THAT APPEARED IN MATHROBHOOMY DAILY DATED 06.06.2018. EXHIBIT P6(A) ENGLISH TRANSLATION OF EXT.P6. EXHIBIT P7 TRUE COPY OF THE ENQUIRY REPORT RECEIVED UNDER RTI ACT. EXHIBIT P7(A) ENGLISH TRANSLATION OF EXT.P7(A) EXHIBIT P8 TRUE COPY OF THE LETTER DATED 1.6.2018 ISSUED BY THE 2ND RESPONDENT TO THE 7TH

RESPONDENT. EXHIBIT P8(A) ENGLISH TRANSLATION OF EXT.P8(A). EXHIBIT P9 COPY OF THE LETTER DATED 1.6.2018 ISSUED BY THE 2ND RESPONDENT TO THE NEW MODERN LABORATORY, WHICH IS MANAGED BY ONE JABBAR A.M. EXHIBIT P9(A) ENGLISH TRANSLATION OF EXT.P9. EXHIBIT P10 TRUE COPY OF THE LETTER DATED 1.6.2018 ISSUED BY THE 2ND RESPONDENT TO BHARATH DIAGNOSTIC LABORATORY MANAGED BY SMT.ALIAMMA C.T. EXHIBIT P10(A) ENGLISH TRANSLATION OF EXT.P10. EXHIBIT P11 TRUE COPY OF THE ORDER NO.C3-3803/18 DATED 7.6.2018 ISSUED BY THE 2ND RESPONDENT. EXHIBIT P11(A) ENGLISH TRANSLATION OF EXT.P11. EXHIBIT P12 COPY OF THE REPORT REFERRED TO IN EXT.P11 DATED 6.6.2018 OF THE DISTRICT LAB TECHNICIAN. EXHIBIT P12(A) ENGLISH TRANSLATION OF EXT.P12. EXHIBIT P13 COPY OF THE INFORMATION ISSUED BY THE 6TH RESPONDENT. EXHIBIT P13(A) ENGLISH TRANSLATION OF EXT.P13. RESPONDENTS EXHIBITS: EXHIBIT R11(A) A TRUE COPY OF THE D&O LICENCE DATED 22.5.2018 ISSUED BY THE VAZHATHOPPU GRAMA PANCHAYAT WITH ENGLISH TRANSLATION. EXHIBIT R11(B) A TRUE COPY OF THE PHOTOGRAPH OF THE BUILDING BEARING NO.10/519. EXHIBIT R11(C) A TRUE COPY OF THE AUTHORISATION DATED 19.12.2018 ISSUED BY THE KERALA STATED POLLUTION CONTROL BOARD IDUKKI OFFICE. EXHIBIT R11(D) A TRUE COPY OF THE ACKNOWLEDGMENT DATED 15.4.2013 ISSUED BY IMAGE. EXHIBIT R11(E) A TRUE COPY OF THE CERTIFICATE ISSUED BY THE INSTITUTE OF LABORATORY TECHNICS AND MODERN CLINICAL LABORATORY, KOTTAYAM. EXHIBIT R11(F) A TRUE COPY OF THE CERTIFICATE ISSUED BY THE SHIRON CLINICAL LABORATORY INSTITUTE VANDIPERIYAR. EXHIBIT R11(G) A TRUE COPY OF THE ORDER OF THE 2ND RESPONDENT DATED 7.6.2018 WITH ENGLISH TRANSLATION. EXHIBIT R7(A) TRUE COPY OF THE LICENSE DATED 12/04/2018 ISSUED BY PANCHAYATH ALONG WITH TRANSLATION EXHIBIT R7(A)1 TRUE COPY OF THE LICENSE DATED 13/04/2018 ISSUED BY PANCHAYATH ALONG WITH TRANSLATION EXHIBIT R7(B) TRUE COPY OF THE AUTHORISATION GRANTED BY THE POLLUTION CONTROL BOARD J.K. DIAGNOSTIC CENTRE. EXHIBIT R7(B)1 TRUE COPY OF THE AUTHORISATION GRANTED

BY THE POLLUTION CONTROL BOARD TO NEW MODERN DIAGNOSTIC CENTRE. EXHIBIT R7(C) TRUE COPY OF THE AUCTION DIARY OBTAINED AS PER RIGHT TO INFORMATION ALONG WITH TRANSLATION. EXHIBIT R7(D) TRUE COPY OF THE PROCEEDINGS OF THE IDUKKI DISTRICT MEDICAL OFFICER ALONG WITH TRANSLATION. EXHIBIT R7(E) TRUE COPY OF THE AFFILIATION GRANTED TO J.K. DIAGNOSTIC CENTRE. EXHIBIT R7(E)1 TRUE COPY OF THE AFFILIATION GRANTED TO NEW MODERN DIAGNOSTIC CENTRE.

EXHIBIT R2(A), TRUE COPY OF THE NOTICES DATED 27.10.2021 EXHIBIT R2(B)& AND ITS ENGLISH TRANSLATIONS ISSUED TO THE EXHIBIT R2(C) RESPONDENTS 7, 8 & 10 AND 9 & 11 TO

IMMEDIATELY CLOSE THEIR CLINICAL LAB COLLECTION CENTRE. //true copy// P.A. to Judge APPENDIX OF WP(C) 5166/2019 PETITIONER EXHIBITS EXHIBIT P1 TRUE COPY OF NOTIFICATION INVITING TENDER DATED 26-4-2013 ISSUED BY THE DISTRICT PANCHAYAT. EXHIBIT P1(A) TRUE COPY OF ENGLISH TRANSLATION OF EXT.P1. EXHIBIT P2 TRUE COPY OF PHOTOGRAPH OF THE BUNKS WHICH ARE NOW BEING USED AS LABORATORIES BY THE RESPECTIVE RESPONDENTS. EXHIBIT P3 TRUE COPY OF LICENSES ISSUED BY THE PANCHAYAT TO RESPONDENTS 8 TO 10 EXHIBIT P3(A) TRUE COPY OF ENGLISH TRANSLATION OF EXT.P3 EXHIBIT P4 TRUE COPY OF PETITIONS SUBMITTED BY THE PETITIONER BEFORE THE DISTRICT COLLECTOR EXHIBIT P4(A) TRUE COPY OF ENGLISH TRANSLATION OF EXT.P4 EXHIBIT P5 TRUE COPY OF PETITION SUBMITTED BY THE PETITIONER DY. DIRECTOR OF PANCHAYAT, THODUPUZHA EXHIBIT P5(A) TRUE COPY OF ENGLISH TRANSLATION OF EXT.P5 EXHIBIT P6 TRUE COPY OF PETITION SUBMITTED BY THE PETITIONER BEFORE SECRETARY, VAZHATHOPPU PANCHAYAT EXHIBIT P6(A) TRUE COPY OF ENGLISH TRANSLATION OF EXT.P6 RESPONDENTS EXHIBITS EXHIBIT R11(A) A TRUE COPY OF THE D&O LICENCE DATED 22.5.2018 ISSUED BY THE VAZHATHOPPU GRAMA PANCHAYAT WITH ENGLISH TRANSLATION. EXHIBIT R11(B) A TRUE COPY OF THE PHOTOGRAPH OF THE BUILDING BEARING NO.10/519. EXHIBIT R11(C) A

TRUE COPY OF THE AUTHORISATION DATED 19.12.2018 ISSUED BY THE KERALA STATED POLLUTION CONTROL BOARD IDUKKI OFFICE. EXHIBIT R11(D) A TRUE COPY OF THE ACKNOWLEDGMENT DATED 15.4.2013 ISSUED BY IMAGE. EXHIBIT R11(E) A TRUE COPY OF THE CERTIFICATE ISSUED BY THE INSTITUTE OF LABORATORY TECHNICS AND MODERN CLINICAL LABORATORY, KOTTAYAM. EXHIBIT R11(F) A TRUE COPY OF THE CERTIFICATE ISSUED BY THE SHIRON CLINICAL LABORATORY INSTITUTE VANDIPERIYAR. EXHIBIT R11(G) A TRUE COPY OF THE ORDER OF THE 2ND RESPONDENT DATED 7.6.2018 WITH ENGLISH TRANSLATION. //true copy// P.A. to Judge APPENDIX OF CON.CASE(C) 672/2019 PETITIONER ANNEXURE ANNEXURE A1 CERTIFIED COPY OF THE INTERIM ORDER DATED 14-06-2018 IN W.P(C) NO. 19741/2018 ANNEXURE A2 PHOTO SHOWING BUNK NO. 8 AUCTIONED BY THE 3RD RESPONDENT ANNEXURE A3 TRUE COPY OF THE COMPLAINT DATED 7-8-2018 SUBMITTED BY THE PETITIONER BEFORE THE 1ST RESPONDENT WITH ENGLISH TRANSLATION. ANNEXURE A3(A) TRUE COPY OF THE AD CARD SIGNED BY THE 1ST RESPONDENT HEREIN. ANNEXURE A4 TRUE COPY OF THE COMPLAINT DATED 5-8-2018

SUBMITTED BY THE PETITIONER BEFORE THE SUB INSPECTOR OF POLICE, IDUKKI POLICE STATION WITH ENGLISH TRANSLATION ANNEXURE A4(A) COPY OF THE RECEIPT DATED 5-8-2018 WITH ENGLISH TRANSLATION. //true copy// P.A. to Judge

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