

## **Implementation of the Preparedness and Upscaling Plan as of 7 April, 2020.**

### **1. Introduction**

The National Health Laboratory Service ("NHLS") is a schedule 3A State Owned Company which was established in 2001 by an Act of Parliament to provide diagnostic pathology laboratory services to the National and Provincial Health Departments. The National Health Laboratory Service (NHLS) is a public health laboratory service with laboratories across South Africa. The NHLS is the largest public health laboratory service with more than 233 laboratories across the nine provinces.

The National Institute for Communicable Diseases (NICD), a division of the NHLS, provides reference microbiology, virology, epidemiology, surveillance and public health research and training in communicable diseases. It serves as a source of information, both during outbreaks and as part of its routine surveillance of priority infectious diseases. A key role is to detect, respond and report timeously during communicable disease outbreaks by providing technical support and reference laboratory diagnostic services. The NICD does not normally provide routine diagnostic service, as that is the function of the NHLS.

Initially the testing for Covid 19 was done by the NICD. When the volume of reference testing started growing and the first positive case was detected, the NICD requested the NHLS to start testing in the NHLS laboratories as from the 6<sup>th</sup> March. The NHLS had capacitated itself through the procurement of state of the art equipment in Virology laboratories in the country.

In addition to the new equipment procured, the NHLS has an instrument called the Roche Cobas 6800 and 8800 which is also used for viral load. A new Corona 19 assay has been brought out which is currently being used in the USA which can be used on this platform. The NHLS rapidly procured and validated this test kit and is currently using the Cobas 6800/8800 to perform CoVid 19 tests.

In addition, the GeneXpert which is used for tuberculosis (TB) testing will also be bringing out an assay in April. The capacity of the GeneXpert equipment will also be used for testing.

The NHLS has done a review of the capacity it will have to implement the roll out of the CoVid 19 testing programme. Both currently and in the future the NHLS will have sufficient capacity to successfully implement

the programme. The NHLS is successfully managing the current demand, and in fact has more capacity than the demand. There is no backlog in testing, and the NHLS has requested that the provinces scale up its screening and referrals for testing.

The NHLS management team had to work under extremely difficult conditions, in the face of global shortages and competition for equipment, to rapidly provide a service to manage the campaign. This had to be done in a very short space of time with instructions to act from the Minister and Cabinet.

## **2. Capacity at NHLS Virology Laboratories**

### **2.1. Capacity on BioRad CFX 96 DX**

The equipment already in use, and for which a diagnostic assay for SARS-CoV-2 was available at the time in January, was considered. The procurement of CFX 96 equipment was strategic and considered standardisation of laboratory equipment. These instruments were rapidly procured in the face of stiff international competition. This also included the procurement of automated or semi-automated extraction of the virus, which will greatly reduce turnaround time.

The first two laboratories which started testing was Groote Schuur Hospital Laboratory and Tygerberg Hospital Laboratory on the 8<sup>th</sup> March and 9<sup>th</sup> respectively. There were three more laboratories testing by the 20<sup>th</sup> March 2020, namely Charlotte Maxeke Johannesburg Academic Hospital laboratory, Universitas Laboratory and Inkosi Albert Luthuli Central Hospital Laboratory. Three more laboratories were added on the 28 March namely Tshwane Academic Laboratory, Dr George Mukhari Laboratory and Port Elizabeth. The total number of laboratories that are currently testing for SARS-CoV-2 using the CFX 96 DX is nine (including the NICD reference laboratory). Altogether there are 12 of these machines, as some laboratories have more than one machine to deal with the workload.

To scale up further, the NHLS has procured a further 12 CFX96<sup>TM</sup> which will bring the total to 24. In addition 6 Nimbus and six EasyMAG extraction instruments were procured for extraction of the virus. The CFX96<sup>TM</sup> current available capacity enables the NHLS to process ~5 000 test in a 24-hour shift.

## 2.2. Capacity on high-throughput Cobas 6800/8800 Roche platforms.

On the 13<sup>th</sup> March 2020, the U.S Food and Drug Administration (FDA) issued an Emergency Use Authorisation (EUA) for the Cobas SARS-CoV-2 test assay. The NHLS currently has 17 Roche Cobas instrument in the laboratories as outlined in the table below. The use of high-throughput assays with short processing times capable of testing large volumes of samples will help meet the demand. The Cobas 6800/8800 analysers are fully automated, interfaced, real-time platforms that facilitates a faster result and turnaround time. The use of these instruments (available spare capacity) will increase the testing capacity of the NHLS to ~15 000 tests performed in a 24-hour shift.

The distribution and capacity of these instruments is outlined in table 1 below.

**Table 1: Distribution of Cobas 6800/8800 and CFX96**

Province	Laboratory	Instrumentation
Gauteng	Charlotte Maxeke JHB Hospital	Four Cobas8800 Two CFX96
	Tshwane Academic	One Cobas8800 One CFX96
Mpumalanga	Rob Ferreira*	Two Cobas8800*
Limpopo	Mankweng	Two Cobas8800
Free State	Universitas	Two Cobas8800 One CFX96
Eastern Cape	Port Elizabeth	One Cobas6800 One CFX96
	Nelson Mandela* Academic	One Cobas8800 One CFX96
Western Cape	Tygerberg	Two CFX96
	Groote Schuur	Two CFX96
	Greenpoint*	One Cobas6800
Kwa-Zulu Natal	Edendale*	One Cobas6800
	IALCH	Two Cobas6800 One CFX
	Ngwelezane*	One Cobas8800
<b>*Not activated as yet</b>		

The model that will be used is similar to the model that the NHLS uses for its HIV viral load programme. The tests must be conducted in specialised virology laboratories, which have specialist virologists overseeing the work. Samples may be collected in any laboratory, and these are then referred to the specialist laboratory. A similar process is used by the private laboratories which have one or two specialised laboratories in their network. Other laboratories will be activated as the need arises.

### **2.3 Capacity on low to high-throughput Cepheid GeneXpert platforms.**

The rapid point-of-care molecular test for detection of SARS-CoV-2, Cepheid Xpert Xpress, has received EUA from FDA on 20 March, 2020. The NHLS has 325 Genexpert instruments with varying capacity in 176 testing laboratories. We are still waiting for the delivery of the testing kits to start with validation during the week of 8 April, 2020. The implementation of this test will increase the testing capacity by another 15,000 tests, to an accumulative ~36 000 tests performed in a 24-hour shift.

### **3. Sampling campaigns**

In an effort to intensify case finding, the NHLS will use the current mobile units to screen contacts and take samples if the person meet the case definition. There is currently seven mobile facilities donated by the Global Fund that is already in the field. An additional 60 mobiles have been purchased and the first 22 have been distributed to the provinces. The rest of the mobiles will be distributed over the next two weeks. The purpose of procuring these mobiles is to provide access to communities. Some mobiles will be used as testing laboratories, and the rest will be used as screening and sampling mobiles. The testing laboratories will be utilised as soon as the GeneXpert test becomes available in the country. It must be noted that not all the tests will be done in the mobiles. The tests samples will be divided between the mobiles and the network of laboratories that the NHLS has according to the number of tests.

The mobiles are staffed with a driver and two nurses each. The nurses have been trained and are competent to take samples from patients. The screening campaign will be driven by the Provincial Departments of Health, with the NHLS playing a supportive role. The Department of Health will determine the number of people to be tested.

### **4. Test Kits**

The NHLS has had to compete for test kits in the international market where both supply, production and delivery was a challenge. Some of the kits were only recently introduced into the market. Through intense negotiations the NHLS has secured a supply of test kits over the next few months that will enable it to meet the upscaling of the campaign.

Currently the NHLS has test kits to do 15,000 tests per day and has secured supplies to enable it to perform the same number of tests over the coming period. The actual number of tests performed however, is determined by the number of people referred for samples to be taken, either by the clinician or by the NHLS.

This depends on the number of people who are screened and who meet the case definition. Whilst the number of people who are referred is increasing through the screening campaign, the total number is not large. The NHLS is confident that as these numbers increase it will be able to suitably manage the load.

#### **4. Partnerships with other Stakeholders**

The response and support for the CoVid 19 has been overwhelming. There have been offers to assist from many stakeholders, and there is strong collaboration between the NHLS, the private sector, the private laboratories, the non-governmental (NGO) sector, organised labour, academic and research institutions, other organisations with laboratories and donors.

The NHLS in collaboration with the Medical Research Council (SAMRC) mapped out the other laboratories that could be utilised, looking at the equipment, and test kits that they have. The approach that the NHLS is using is two- pronged: Firstly the NHLS will fully utilise the NHLS laboratory capacity and if that capacity is exceeded the capacity in other laboratories will be utilised. Secondly where other laboratories have other functionalities and test kits that will enhance the testing capacity of the NHLS, this is welcomed.

The NHLS is in discussions with a number of laboratories including the CSIR, academic and research laboratories, and agricultural laboratories. The offers of assistance are highly welcomed, including the offers of assistance for the mobile laboratories, and the support from the private sector.