

**THE WEST BENGAL CLINICAL ESTABLISHMENT  
REGULATORY COMMISSION.**

**Present: Justice Ashim Kumar Roy, Chairperson.**

**Dr. Sukumar Mukherjee, Member.**

**Dr. Madhusudan Banerjee, Member.**

**COMPLAINT ID: HGY/2017/000200.**

**SK. Asif Ahmed .....Complainant.**

**-versus-**

**Doyen Diagnostic & Research Foundation & others.....Respondents**

**Date of judgment: 16<sup>th</sup> March, 2018.**

**J U D G M E N T.**

A complaint was lodged before the Commission by Sk. Asif Ahmed of District Hooghly, against Doyen Diagnostics & Research Foundation alleging that on 26.6.2017 blood tests were done, amongst other for ANF (Anti Nuclear Factor) against payment. According to the said report, the result was positive. On the basis of such report, treatment and medication commenced. Subsequently, on August 16, 2017, a blood test was done amongst other for ANF Profile at IPGME&R, SSKM Hospital and this time the impression was negative.

The further case of the complainant that on the basis of such wrong report of Doyen Diagnostics & Research Foundation, he has to undergo medical treatment and to consume different medicines. Not only the unnecessary medication was injurious to his health and caused immense adverse effects, that wrong result also put him to severe mental trauma and suffering. It is claimed that he may be sufficiently compensated by Doyen Diagnostics & Research Foundation for their deficiencies in service.

2. On receipt of the complaint, notice was issued against the Clinical Establishment and the pathologist who conducted the tests, seeking their comments on the allegation made against them.
3. In response to the notice, the Doyen Diagnostics & Research Foundation filed their reply denying the allegations made against it. It is submitted that there was no lapse or mistake in the test done and report showing ANF positive was absolutely correct. It is further added that the test at their laboratory was done on June 26, 2017 and the test at IPGME&R, SSKM Hospital which shows the impression negative was done nearly 50 days after on August 16, 2017. In the mean time the complainant was under prolong medications and due to that the ANF reduced to normal.
4. In addition to above, Dr. Animesh Ghosh, pathologist who conducted the test, in writing clarified the issues and stated as follows.
  - a) First, of all the ANA Positive result given in their laboratory was in June, 2017, while the negative ANA reported outside was in September, 2017 (as per the documents supplied by the complainant). So it is evident that after 2 months interval the test was done and by this time ANA and other markers can became negative indeed – false positive ANA-s are also found in 03-15% of healthy individuals (Ref: America College of Rheumatology). Single positive ANA does not indicate presence of SLE or autoimmune disorders.
  - b) Few viral infections can show positive ANA-s as in hypothyroidism, even cancers. Thus it is imperative that a positive ANA should warrant an immediate battery of autoimmune testing (which was not done in this case) and merely having a positive ANA does not necessarily mean SLE/Autoimmune disorder.
5. We have given our anxious and thoughtful consideration to the rival submissions of the parties. The materials on record have been very carefully perused.
6. In our opinion, the complainant has failed to establish his case. The first test for ANF giving the impression positive was done on June 26, 2017 at Doyen Diagnostics & Research



Foundation and the second one at IPGME&R, SSKM Hospital was done nearly 50 days after on August 16, 2017. It is already known that ANF test done by ELISA (Enzyme immuno assay) is a screening test in the general population but it lacks specificity in terms of diagnosis of SLE. The immunofluorescent method with Hep 2 test ANF in blood has higher specificity for diagnosis as it was done at IPGMER-SSKM Hospital. This has relevance to initiate additional tests to confirm SLE and proceed to plan treatment of SLE. Hence the discrepancy between the two tests may happen in scientific practice. This cannot be taken as deficiency of service of clinical establishment.

7. For the reasons stated above, we do not find any merit in this complaint and the same stands dismissed.

Sd/-

Justice Ashim Kumar Roy  
Chairperson.

Sd/-

Dr. Sukumar Mukherjee, Member.

Sd/-

Dr. Madhusudan Banerjee, Member.



*16/3/2018*  
Secretary  
W.B.C.E.R.C.  
Kolkata-1