HFEA Executive Licensing Panel Meeting

2 May 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 3

Centre 0321 – (NewLife Fertility Centre) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
David Moysen – Head of IT	**Also in attendance:**
Nick Jones – Director of Compliance & Information	Sam Hartley – Head of Governance & Licensing
	Sue Gallone – Director of Finance & Resources

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the NewLife Fertility Centre is located in Epsom, Surrey and has held a licence with the HFEA since August 2011. The centre provides a full range of fertility services.

2. The Panel noted that the centre is currently on a three-year licence, due to expire on 2 August 2016.

3. The Panel noted that in the 12 months to 31 December 2013, the centre provided 217 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

4. The Panel noted that HFEA held register data for the year ending September 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with the national average.

5. The Panel noted that in 2012 the centre reported five cycles of partner intrauterine insemination with one pregnancy, which is in line with the national average.

6. The Panel noted that for the year 2013 the centre reported 48 cycles of partner insemination with five pregnancies, none of which resulted in a multiple pregnancy. The HFEA analysis of the sector's results for 2013 had not yet been performed, therefore a comparison of the centre's 2013 results against the national average could not be made.

7. The Panel noted that the interim inspection took place on 5 February 2014.

8. The Panel noted that during the last renewal inspection in March 2013, the Inspectorate had concerns about the relatively low levels of treatment activity and the considerable number of non-compliances identified at the centre since it was first licensed. The Panel noted that the Inspectorate recommended the centre's licence was renewed for a shorter period of three years and that the centre work closely with the HFEA to correct the non-compliances identified. The Inspectorate also recommended that a targeted unannounced interim inspection be performed within a year of the licence renewal date to review evidence of implementation of the recommendations. These recommendations were endorsed by the Executive Licensing Panel on 21 June 2013, when the centre's licence renewal application was considered.

9. The Panel noted that the Person Responsible (PR) had provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, the inspection in February 2014 identified concerns that corrective actions required relating to witnessing, consent, screening and semen analysis had not been effective. The Panel also noted that the centre had not embedded an effective quality management system.

10. The Panel noted that at the time of inspection seven major areas of non-compliance were identified. The Panel noted the steps the PR had taken to address the non-compliances and urged the PR to fully implement the recommendations within the prescribed timescales.

11. The Panel acknowledged the patient feedback responses and that whilst they were predominantly positive, concern was raised regarding the emergency out of hours phone service.

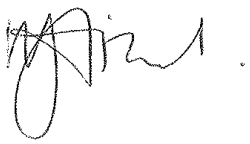
12. The Panel noted the Inspectorate's recommendation that a focused unannounced interim inspection is performed within 12 months and that if the centre is not able to demonstrate progress in implementing the recommendations at that point, it may be referred back to a Licensing Committee with recommendations for possible regulatory sanctions, subject to management review.

13. The Panel noted the Inspectorate's consideration of whether it was appropriate to recommend the continuation of the licence, and further its recommendation of the continuation of the centre's licence.

Decision

14. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (including embryo testing) and Storage Licence continued.

15. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions. The Panel agreed that the centre should be closely monitored with a focused unannounced interim inspection performed within 12 months.



Signed: Date: 19 May 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: **NewLife Fertility Centre**
Centre number: **0321**
Date licence issued: **03/08/2013**
Licence expiry date: **02/08/2016**
Additional conditions applied to this licence: **None**
Date of inspection: **05/02/2014**
Inspectors: **Ms Janet Kirkland (Lead), Ms Sara Parlett**
Date of Executive Licensing Panel: **02/05/2014**

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced focused interim inspection together with our assessment of the centre's performance based on other information. We usually do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

This report represents an evaluation of a centre's performance based on the above.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel (ELP) is asked to note that at the time of the inspection there were recommendations for improvement in relation to seven 'major' areas of non-compliance as follows:

'Major' areas of non compliance:

1. the PR should ensure that patients are given sufficient information to inform consent and that consent decisions are recorded clearly and accurately;

2. the PR should ensure that the disposal of gametes and embryos is witnessed;

3. the PR should ensure that welfare of the child (WoC) assessments are performed and clearly documented within the patient record;

4. the PR should ensure that the consented storage periods documented on the centre's database and bring-forward system correspond with the storage consent documented in the patient records;

5. the PR should review audit procedures to ensure that they are robust and effectively audit the practices used for critical activities and their compliance with regulatory requirements;

6. the PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA;

7. the PR should ensure that blood results accepted by the centre have been performed in a suitably accredited laboratory.

The PR has given a commitment to implement the recommendations.

Considerable improvement is required in some key areas of practice. Progress towards more effective practice has not been sustained since the licence was initially granted in 2011. In particular, the Executive is concerned the centre has not, as yet, embedded an effective quality management system. The Executive carefully considered whether it was appropriate to recommend the continuation of the licence. The inspection team recommends the continuation of the centre's licence and, in addition, that the ELP requests that a focused unannounced interim inspection be performed by the Executive within twelve months.

If the centre is not able to demonstrate progress in implementing the recommendations at that point then, subject to a management review, it may be

referred back to a licensing committee with recommendations for possible regulatory sanctions.

Information about the centre

The NewLife Fertility Centre is located in Epsom, Surrey and has held a licence with the HFEA since August 2011.

The centre provides a full range of fertility services.

The centre provided 217 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/12/2013. In relation to activity levels this is a small centre.

Following the renewal inspection of the centre in March 2013, the inspection team had concerns about the relatively low levels of treatment activity at the centre since it was first licensed and the considerable number of non-compliances identified. The inspection team recommended licence renewal for a shorter licence period of three years; that the centre work closely with the HFEA to correct the non-compliances identified, and; that a targeted unannounced interim inspection be performed within a year of the licence renewal date.

These recommendations were endorsed by the ELP on 21/06/2013 which renewed the centre's licence.

This interim inspection provided an opportunity to review evidence of implementation of the recommendations made in the report of the renewal inspection in March 2013.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending September 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

In 2012 the centre reported five cycles of partner intrauterine insemination with one pregnancy. This success rate is in line with the national average.

For the year 2013 the centre reported 48 cycles of partner insemination with five pregnancies, none of which resulted in a multiple pregnancy. The HFEA analysis of the sector's results for 2013 has not yet been performed; therefore a comparison of the centre's 2013 results against the national average cannot be made yet.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy.

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate rates for all IVF, ICSI and FET cycles for all age groups was 27%. This represented performance that was not statistically different from the 15% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error do not occur. The following laboratory activities were observed in the course of the inspection: preparation for embryo transfer. This procedure was witnessed in accordance with HFEA requirements using both electronic and manual witnessing systems.

The inspection team was able to review witnessing records that were present in five sets of patient notes and concluded that records of both manual and electronic witnessing are accurately maintained, with one exception, this being that in three out of five of the records reviewed the disposal of gametes/embryos had not been witnessed. This was noted as an area of concern at the previous inspection (See recommendation 2).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by ten patients were reviewed in the course of the inspection. The following issues were noted:

- Three of the consent decisions documented in the patient's files did not correspond to those recorded on the HFEA register; in each case the disclosure consent form in the patient files indicated that consent had been given but the data submitted to the HFEA register recorded that it had been withheld.

- In six of the records reviewed it was apparent that the instructions on the completion of the consent form by the patient had not been adhered to. This resulted in centre staff inputting the data to the HFEA register having to use an element of judgment in determining the decision of the patient. The decisions recorded in the HFEA register mean that patient details will not be released without their consent, however this issue raised concern that the completion of the consent form and the implications of the consent decision are not being explained effectively to patients.

This was noted as an area of concern at the previous inspection (See recommendations 1 and 6).

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that stored gametes and embryos are within their consented storage period. The storage expiry dates for three sets of embryo/gametes

were cross checked between the centre's database and the storage consent forms in patient notes. In two cases, the storage consent expiry date recorded on the database was the same as that documented in the storage consent forms and the embryos/gametes were being stored in accordance with consent. In a third case, the embryo storage consent expiry date logged on the database was December 2023 but the storage consent form documented an expiry date in August 2014. The centre's bring-forward system for giving the gamete providers sufficient notice of the end of the consented storage period had also not been initiated. This issue raises concerns that the centre may not currently be able to manage its stored material effectively in accordance with the consent decisions of the gamete providers (See recommendation 4).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction.

Patient experience

During the inspection visit there was no opportunity to speak directly to patients however the inspection team did review the centre's own documented assessment of patient feedback. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Two of the individuals providing written feedback to the HFEA commented that they had compliments about the care that they received including the caring and professional approach that they experienced; they also indicated that they would recommend the centre to others.

The centre's own patient feedback responses were predominantly positive, some referring to "excellent overall care". There was however concern raised regarding the emergency out of hours phone service.

During an audit of patient records it was noted that concern had also been raised by a patient regarding the emergency out of hours telephone service provided by the centre. There had been a delay of one and a half hours in a patient's call being returned. This was investigated by the centre. Whilst the inspection team has not made a recommendation in relation to this, it was discussed in the feedback session and the PR was encouraged to review the provision of this service to ensure that the system to respond to emergency out of hours phone calls is improved.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

Whilst performing an audit on five sets of notes the following issues were noted:

1. Check lists in patient files indicated that the welfare of the child had been assessed. However, a formal record of the assessment was not present for three patients. In one instance the WoC form had been completed by the patient but not by centre staff (See recommendation 3).

2. In two cases, the male treatment form (MT) and the female treatment form (WT) were not fully completed by the patient. It is important to state that these errors did not result in treatment being provided without consent but raised concern that the consents were not being properly explained to patients and/or checked by centre staff (see recommendation 1 and comment re. checklist completion below).

3. The centre uses a checklist to ensure appropriate information has been provided and that consents, WoC assessment and screening have been completed prior to treatment. The checklists were all fully completed and signed off in all patient notes, despite the errors documented above in some patient notes. Discussions with centre staff raised concern that there was some uncertainty as to the meaning of a tick on a check list: i.e. did it mean that the relevant forms had been given to the patient or that they had been returned and were present in the record having been completed correctly and appropriately (See recommendation 5).

4. During a review of patient notes, in three of the notes it was not clear if the blood test results were from a laboratory which is CPA accredited. This was identified as a non-compliance at the previous inspection (See recommendation 7).

5. The inspection team compared the results of their audit of consent to disclosure decisions with an audit performed by the centre on the same set of patient notes for the same time period; discrepancies in the findings of the two audits were noted. This was discussed with the quality manager who reviewed the notes and agreed with the findings of the inspector. This, in addition to the observations made regarding the use of checklists and discrepancies identified in the witnessing audit performed by the scientific inspector, led the inspectors to consider that in these instances the centre's audit procedures had not been robust or effective (See recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in March 2013, recommendations for improvement were made in relation to seven major and eleven 'other' areas of non-compliance.

The PR had provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, as noted in the body of the report,

the evidence seen on inspection identified concerns that the corrective actions relating to four of the non-compliances had not been effective, these being:

- The PR should ensure that the disposal of gametes and embryos is witnessed (see recommendation 2). It is noted that the laboratory manager appears to have misunderstood recent guidance issued in a HFEA clinic focus article and was of the opinion that the need to witness the disposal of gametes had been relaxed.

- The PR should ensure that patients are given sufficient information to inform consent and that the relevant consent decisions are recorded clearly and accurately (see recommendation 1).

- The PR should ensure that screening and semen analysis results accepted by the centre have been performed in a suitably accredited laboratory (see recommendation 7).The PR explained that he believed that guidance was available which indicated that general practitioners only use CPA accredited laboratories for assessment of samples. The inspector is not aware of this guidance but would be happy to review the recommendation if the PR can provide a copy of the guidance to the HFEA.

- The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA (see recommendation 6).

On-going monitoring of centre success rates

Since the previous inspection in March 2013 this centre has not received any requests via the risk based assessment tool (RBAT) to review procedures for the provision of specific treatments.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The HFEA information team consider that the centre is broadly compliant with register submissions and recommendations are not necessary.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None noted on inspection			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. In two out of five records reviewed on inspection it was noted that the male treatment form (MT) and the female treatment form (WT) were not fully completed by the patient. This raised concern as to whether the consents were being properly explained to patients and checked accordingly (SLC T58). In addition it was apparent in the audit of consent to disclosure that the basic instructions on the completion of the consent form had not been adhered to. This raises concern that the completion of	The PR should review the centre’s procedures for the provision of information prior to providing consent and for the completion and documentation of consent. The PR should also review the process by which staff check the consent forms to ensure that consent decisions are clear and accurately reflect the patient’s wishes. The PR should ensure that staff are trained and competent in providing information and obtaining consent The PR should provide the HFEA with evidence of the full	The PR ,General Manager & Nurse Manager will review processes and procedures to ensure compliance. Staff have been trained, further training will be provided alongwith the required audits.	The inspector looks forward to receiving evidence of the implementation of the recommendations including a copy of the audit results including corrective actions and timetable for their implementation. Further action required.

the consents and the implications of the consent decisions are not being explained effectively to patients by a team member who is competent to do so (SLC T58).	implementation of the recommendations by 5 May 2014. The PR should perform a full audit of consenting processes and documentation for a period after the actions above have been implemented. The centre's inspector should be provided with a copy of the audit report, including corrective actions taken, by 5 August 2014.		
2. It was noted in three out of five of the records reviewed on inspection that the disposal of gametes/embryos had not been witnessed (SLC T71 and CoP Guidance 18.4 (j)). This was noted as a non-compliance at the previous inspection in March 2013. It is recognised that failure to witness the disposal of gametes/embryos does not	The PR should take immediate action to ensure that the disposal of gametes and/or embryos is witnessed. The PR should provide the HFEA with assurance that this recommendation has been actioned by the time that he responds to the report.	This was discussed at the inspection. Disposal of cryopreserved samples is witnessed at Newlife. Newlife requested clarification regarding dish discard and the stages during the treatment cycle at which the HFEA thought that this should include a witness step. Newlife is keen to ensure the security and safety of it's patients and will consider the advice and	The lead inspector acknowledges the PR's request for clarification from the HFEA. Guidance Note 18 of the CoP was amended in October 2013 to put an emphasis on centres taking responsibility for witnessing procedures in their local environment (Chair's Letter CH(13)01). A Clinic Focus article published in September 2013 gives clarification regarding disposal

pose a risk of gametes/embryos being misidentified and in consideration of this and explanations provided by centre staff around the decision not to witness this step, that the non-compliance has not been categorised as critical.		clarification provided by the HFEA regarding discard of dishes that have been used for culture of embryos. Review of current practice and implementation of any appropriate changes will then be made.	of gametes and embryos. In summary, this states that the HFEA does not require centres to witness the disposal of containers that *have* held gametes or embryos. However, where containers currently hold gametes or embryos, then cross checking of information in patient records against what is on the container is required prior to disposal. The PR should undertake a review of the centre's witnessing procedures to ensure they comply with relevant guidance. A summary report of the review findings, including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 5 May 2014.
3. Check lists in patient files indicated that the welfare of the child had been assessed. However, a formal record of the assessment was not present for	The PR should ensure that WoC assessments are performed for all patients. The PR should undertake an	WOC are carried out on all patients but the centre will ensure this is clearly indicated with signatures completed fully.	The inspector looks forward to receiving a copy of the audit report including any corrective actions and the timescale for their implementation.

three patients. In one instance the WoC form had been completed by the patient but not by centre staff (SLC T56).	audit of patient records for evidence that the WoC has been assessed and documented appropriately. The PR should provide the HFEA with a copy of the audit report including any corrective actions and the timescale for their implementation, by 5 May 2014.		Further action required.
4. In one case, the storage consent expiry date logged on the centre's storage database was in December 2023 whereas the expiry date documented by the gamete providers in their storage consent forms in their notes was August 2014 (SLC T46). The centre's bring forward system had not been initiated because of this error. This raises concerns that the centre may not be able to manage its stored material in accordance with the consent decisions of the gamete providers. It also	The PR should ensure that the storage consent expiry dates documented on the centre's database correspond with the decisions recorded on consent forms in the patient's notes. The PR should review the circumstances that led to this error and ensure that there are systems and processes in place to prevent a recurrence. The PR should, for all stored gametes and embryos, audit the storage consent expiry dates documented on the centre's database against those	This incidence is less than 1% of samples in storage. No samples are stored beyond their consented expiry date. This was disucssed at inspection and confirmed as an error when adding expiry dates to the IDEAS database when the frozen embryos were imported. This was discussed and suggested by the Lab Manager at inspection. As part our move from IDEAS to	The inspector looks forward to receiving the results of the audit including any corrective actions and the timescale for their implementation. Further action required.

risks storing gametes and embryos without the effective consent of the gamete providers (SLCs T79 and T82).	documented in storage consent forms in the patient records. The PR should provide the HFEA with the results of the audit including corrective actions by 5 August 2014.	Meditex database all consents for stored material are being audited and scanned onto Meditex with a 'Cryo contract' being set up which will allow alert of storgage date expiry. This will become normal practice for all future cryopreservation events and will ensure correct storage expiry dates are apparent and bring forward initiation is activated.	
5. Observations made by the inspection team raised issues as to the effectiveness of the centre's audit processes and accurate use of check lists, as described in the body of the report (SLC T36).	The PR should review the centre's audit process. The PR should ensure that audits are performed by staff competent to do so. The PR should ensure that audits are robust, comprehensive and satisfy the full scope of SLC T36. The PR should document the findings of the review and inform the inspector of any corrective actions by 5 May 2014.	The checklists are known to the nurses and those working at the clinic but will be adapted so the intent of the checklist is clear to all parties who look at the notes. further audits will be carried out as advised	The PRs response is acknowledged but it is reiterated that that recommendation relates not simply to the failure to complete checklists effectively but to the failure of the centre's audit procedures to identify the issue. This is the rationale for requiring the review of audit procedures. The inspector looks forward to receiving a record of the outcome of the review of the centre's audit process.

	The PR should review the use of the patient checklist and ensure that it is used consistently and accurately by all staff. The PR should provide the HFEA with the outcome of this review and any corrective actions required by 5 May 2014.		Further action required.
6. Three of the consent to disclosure to researchers decisions documented in the patient's files did not correspond to those recorded on the HFEA register. The disclosure consent form indicated that consent had been given but the data submitted to the HFEA's register documents that consent had been withheld (HF&E Act 1990 (as amended) Section 33A). This was noted as a non-compliance at the previous inspection in March 2013 and for this reason the non-compliance has been categorised as major rather	The PR should ensure that staff are trained and competent in the submitting consent to disclosure decisions to the HFEA. Following the completion of the training the PR should perform an audit of the consent decisions against those recorded at the HFEA The PR should inform the HFEA of the audit results by 5 May 2014.	The Nurse Manager has undertaken staff training in the past and conducted audits. Further training and audits will be undertaken . There was some confusion has been clarified with Neil McComb	The Inspector looks forward to receiving the results of the audit including any corrective actions and the timescale for their implementation. Further action required.

than “other” as is usual.			
7. The PR could not confirm that blood test results accepted by the centre had been performed in a suitably accredited laboratory (SLC T21). This was also noted as a non-compliance at the previous inspection in March 2013 and for this reason the non-compliance has been categorised as major rather than “other” as is usual..	The PR should ensure that test results used by the centre for diagnostic purposes are performed by appropriately accredited laboratories. The inspector should be advised of the measures taken to ensure that this happens by the time the PR responds to the report.	In the interests of minimising costs to patients, the patient is given the opportunity to have blood tests done by their GP. 3 GP surgeries were telephoned, who confirmed that the blood tests were sent the local Trust NHS hospital. The Trust has provided the clinic with proof of CPA accreditation .We will advise patients that results must be on headed paper and certified by their GP	Whilst the inspector acknowledges the centre’s actions to ensure that blood test results accepted by the centre had been performed in a suitably accredited laboratory; headed paper from a general practitioner would not necessarily provide this confirmation. The centre should consider asking for the actual copies of the blood results provided by laboratory providing the analysis .It would then be possible for the centre to check that the laboratory is indeed accredited.

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None noted on inspection			

Additional information from the Person Responsible